EFFECTIVENESS OF CONTRAST BATH ON LEVEL OF NEUROPATHY PAIN AMONG CLIENTS WITH DIABETES MELLITUS ATTENDING DIABETIC OUTPATIENT DEPARTMENT AT SELECTED HOSPITAL, CHENNAI.

DISSERTATION SUBMITTED TO

THE TAMIL NADU DR.M.G.R. MEDICAL UNIVERSITY

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IN PARTIAL FULFILLMENT OF REQUIREMENT FOR THE DEGREE

OF

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LIST OF ABBREVATIONS

ADA	-	American Diabetes Association
CAD	-	Coronary Artery Disease
CVD	-	Cardio Vascular Disease
DM	-	Diabetes Mellitus
DPN	-	Diabetic Painful Neuropathy
DR	-	Diabetic Retinopathy
GNP	-	Galer Neuropathy Pain Scale
IASP	-	International Association for the Study of Pain
ICCR	-	International Centre For Colloborative Research
ICMR-INDIAB	-	Indian council for medical research - India diabetes study
IDF	-	International Diabetes Federation
IFB	-	Impaired Fasting Glucose
IGT	-	Impaired Glucose Tolerance
NCD	-	Non Communicable Disease
NDS	-	Neurological Disability Score
NIDDM	-	Non Insulin Dependent Diabetes Mellitus
NSS	-	Neuropathy System Score
PVD	-	Peripheral Vascular Disease
T2DM	-	Type 2 Diabetes Mellitus
USA	-	United States of America
UK	-	United Kingdom
WHO	-	World Health Organization

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Effectiveness of contrast bath on level of neuropathy pain among clients with diabetes mellitus attending diabetic outpatient department at selected hospital, Chennai.

Aim and objective: To assess the effectiveness of contrast bath on level of neuropathy pain among clients with diabetes mellitus. **Methodology**: Experimental between group pre test- post test research design was adopted to assess the effectiveness of contrast bath among 60 clients with diabetes mellitus who satisfied the inclusive criteria and attending diabetic outpatient department at Sir Ivan Stedeford Hospital-Ambattur. The samples were selected based on simple random sampling – lottery method. Contrast bath (alternate immersion of feet in hot water for 3 minutes and cold water for 1 minute) was provided in 5 cycles with the total duration of 20 minutes. The pre and post test level of neuropathy pain was assessed by using Galer Neuropathy Pain Scale. **Results**: The findings of the study showed, that the post test level of neuropathy pain, the mean value of the experimental group was 21.93 with the standard deviation of 5.44 and the mean value of control group was 72.73 with the standard deviation of 7.15. The calculated 't' value (30.90) was higher than the table value which indicated, that there was a high statistically significant difference in the post test level of neuropathy pain among clients with diabetes mellitus between experimental and control group at $p<0.001$ level. **Conclusion:** The result showed that there was a significant reduction in the level of neuropathy pain among clients with diabetes mellitus after administration of contrast bath in the experimental group. Thus contrast bath was an effective intervention in reducing the level of neuropathy pain among clients with diabetes mellitus.

***Key words**: contrast bath, level of neuropathy pain, clients with diabetes mellitus*

INTRODUCTION

In the 21st century with advancing technology, taking care of one's own health is gaining more emphasis because there is growing awareness regarding health among every person in the world. Both communicable and non communicable disease plays an equally important role in increasing the mortality and morbidity rate.

Diabetes mellitus is a complex, chronic illness requiring continuous medical care with multi factorial risk reduction strategies beyond glycemic control. **(The American Diabetes Association, 2014).**

Majority of the people with diabetes around 382 million are aged between 40 and 59, 80% of them live in low- and middle-income countries. Every six seconds a

person dies from diabetes. Diabetes caused 5.1 million deaths in 2013. By 2035, type 2 diabetes in particular will increase by 55% . **(International Diabetes Federation ,2013)**

Various non pharmacological treatments are available to reduce the level of neuropathy pain which includes yoga, exercise, contrast bath, foot massage therapy, acupuncture and acupressure.

Contrast bath, also known as alternate bath , allegedly promotes the cyclic vaso constriction and vasodilatation and enhances the reduction of neuropathy pain in clients with diabetes mellitus. Protocols may involve alternate immersion of feet in warm water and cold water. Protocols may differ with respect to who performs the contrast bath and climatic changes in which it is performed. Professionals who may provide the service include nurses, occupational therapists and physical therapists. In some cases, family members and clients may be trained in the techniques and are given primary responsibility for providing the therapy. Treatment may be delivered in the hospitals, nursing home and at patients home.

OBJECTIVE

To determine the effectiveness of contrast bath on level of neuropathy pain among clients with diabetes mellitus.

METHODOLOGY

Research design: Experimental between group pretest- posttest research design

Variables:

Independent variable - contrast bath

Dependent variable - level of neuropathy pain

Setting: Sir Ivan Stedeford Hospital-Ambattur

Population: The population of the study includes the client with type I or type II diabetes mellitus with 5 years chronicity and having neuropathy pain, attending diabetic outpatient department at Sir Ivan Stedeford Hospital-Ambattur.

Sampling: The sample size of the study consists of 60 clients with diabetes mellitus (who fulfil inclusion criteria). Simple random sampling technique was adopted. The study included the clients with type I or type II diabetes mellitus since >5 years and having neuropathy pain. The study excluded the clients with diabetes mellitus who were already exposed to contrast bath.

Instruments used in the study

Galer Neuropathy Pain Scale was used to assess the level of neuropathy pain.

Intervention

The investigator administered contrast bath for experimental group by alternate immersion of feet in warm water (100°-105° F) for 3 minutes, and cold water (60°-70°F) for 1 minute and repeated for 5 cycles with the duration of 20 minutes. The control group was subjected to the hospital routine.

RESULTS

The findings of the study revealed that, when comparing the post test level of neuropathy pain among clients with diabetes mellitus between the experimental and control group, the mean value of the experimental group was 21.93 with the standard deviation of 5.44 and the mean value of control group was 72.73 with the standard deviation of 7.15. The calculated 't' value (30.964) was higher than the table value which indicated, that there was a high statistical significant difference in the post test level of neuropathy pain among clients with diabetes mellitus between experimental and control group at $p<0.001$ level.

The study findings were analyzed by means of one way analysis of variance and unpaired t-test. The one way ANOVA 'F' test and unpaired't' test was used for association. In the experimental group the calculated 'F' value indicated that there was no significant association with the selected demographic variables except for family income and whereas for control group, there was no significant association with all selected demographic variables.

DISCUSSION

There was a significant improvement in reducing the level of neuropathy pain among clients with diabetes mellitus in the experimental group after providing contrast bath. This may be due to cyclic vasoconstriction and vasodilatation which reduces the pain. Thus the contrast bath was an effective intervention in reducing the level of neuropathy pain among clients with diabetes mellitus.

CONCLUSION

The findings proved that contrast bath was effective in reducing the level of neuropathy pain among clients with diabetes mellitus. Therefore the intervention tool can be utilized by the health care professional in their practice at the diabetic outpatient department and in medical wards.

IMPLICATIONS FOR CLINICAL PRACTICE

Neuronurse specialist can formulate separate protocol for contrast bath and implement in their daily routine. The nurse administrator can allot separate budget for inservice education to disseminate the research findings to all nurses. As a nurse educator. The major study finding can be incorporated in the nursing curriculum at various level to develop and equip the students to identify the negative perceived health status and health related behaviours among client with diabetes mellitus.

INTRODUCTION

The rapid advances in technology in the 21st century has placed greater emphasis on taking care of one's own health because there is growing awareness regarding health among every person in the world. Both Communicable and Non Communicable Diseases (NCD) play an equally important role in increasing the mortality and morbidity rate. We are facing many non- communicable diseases (silent killer) caused by unhealthy habits, under nutrition and also by over nutrition. The **66th World Health Assembly** reported that non communicable disease acknowledges the global burden; hence they started a project in May 2013 by conducting free camps for screening and treating the clients affected with NCD.

Among non communicable diseases, Diabetes Mellitus (DM) is a huge, growing problem and health care costs to society is high and escalating. **International Diabetes Federation (IDF) and World Health Organization (WHO)** started the World Diabetes Day on 14 November to mark the birthday of Fredrick Banting discoverer of insulin, a life-saving treatment for diabetes. **World Diabetes Day** increases the universal awareness of diabetes – it's growing rates around the globe and prevention of the disease. The theme for world diabetes day 2013 is *"Prevent diabetes: protect our future"*

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Diabetes mellitus is a complex, chronic illness requiring continuous medical care with multi factorial risk reduction strategies beyond glycemic control. **(The American Diabetes Association,2014).**Diabetes mellitus is a chronic multisystem disease related to abnormal insulin production, impaired insulin utilization or both. The prevalence of diabetes for all age groups worldwide was estimated to be 2.8% in 2000 and may reach 4.4% in 2030. Majority of the people with diabetes around 382 million are aged between 40 and 59, 80% of them live in low- and middle-income countries. Every six seconds a person dies from diabetes. Diabetes caused 5.1 million deaths in 2013. By 2035, type 2 diabetes in particular will increase by 55%. **(IDF,2013)**

BACKGROUND OF THE STUDY

WHO (2013) reported that 347 million people worldwide had diabetes. Majority 80% of people with diabetes live in low and middle income countries. As per the project report, death due to diabetes will double between 2005 and 2030. Neuropathic pain exerts a significant impact on quality of life, sleep, daily activities, and enjoyment of life. Chronic neuropathic pain is present in 13–26% of diabetic patient. India is the second highest populated country and has the highest number of diabetic patients followed by China and USA.

Table 1: Global prevalence of diabetes mellitus - IDF, 2013

Country	**Millions**
China	98.4
India	65.1
USA	24.4
Brazil	11.9
Russian	10.9
Mexico	8.7
Indonesia	8.5
Germany	7.6
Egypt	7.5
Japan	7.2

In India an unprecedented rise in diabetes prevalence is the outcome of lifestyle changes in the background of genetic predisposition. There is a extensive regional difference in diabetes prevalence and management. The highest prevalence of diabetes mellitus (DM) was noticed in southern region (Ernakulum, Kerala) and lowest prevalence was observed in North Eastern region (Manipur). Similarly huge variations have been marked in overall awareness and diabetes care across the geographies within India. The regional challenges are mainly affected by poor disease attentiveness, socioeconomic inequality and underutilization of the public health-care services.

A recent **diabetic survey in India (2013),** showed Diabetes mellitus prevalence in Karnataka and Hyderabad was 12.9% and 16%. The total percentage of diabetes mellitus was 19.78%, 16.06% in males and 22.04% in females of Karnataka, India. The overall weighted prevalence of diabetes in Tamil Nadu was 10.4 per cent, Jharkhand 5.3 per cent, Chandigarh, 13.6 per cent and Maharashtra 8.4 per cent.

Amrita Diabetes and Endocrine foundation (2013), conducted a population survey in urban areas of Ernakulum (Kerala) district showed prevalence of diabetes as 19.5%. Results from another study carried out in rural Kerala showed crude and age-adjusted prevalence to be 14.6% and 12.5%, respectively, whereas Impaired Fasting Glucose (IFG) was found to be 5.1% and 4.6%, respectively.

Many complications arise out of diabetes. It is classified mainly into acute and chronic. Chronic is further classified as micro and macro vascular.

A) Microvascular complication includes coronary artery disease, neuropathy, nephropathy and retinopathy.
B) Macrovascular microvascular includes stroke, peripheral vascular disease and diabetic myonecrosis

Diabetes can affect the foot due to neuropathy, peripheral vascular disease and infection. About 60 to 70% of people with diabetes mellitus have different forms of nervous system damage which often includes impaired sensation or pain in the feet or hands. **American Diabetes Association (ADA)2014,** defined diabetic neuropathies as "the presence of symptoms and/or signs of peripheral nerve dysfunction in people with diabetes after exclusion of other causes".

The **International Association for the Study of Pain (IASP, 2014)**, has defined neuropathic pain as "pain initiated or caused by a primary lesion or dysfunction in the nervous system".

Diabetic neuropathies are common in clients who have hyperglycemia, hyperlipidemia, hypertension and obesity.

A rise in prevalence of diabetes was observed in Chennai from 13.5% (2000) to 18.6% (2013) whereas the prevalence of IGT(Impaired Glucose Tolerance) decreased from 16.8% (2000) to 7.4% (2013). Kancheepuram district reported 16.7% of diabetes and 4.3% IGT prevalence in 2013. The rise in diabetes prevalence rates from 2000 to 2013 suggests the high conversion rates of prediabetes to diabetes. **(Chennai Survey Report, 2013).**

Recent **Indian council of medical research-India diabetes study (ICMR INDIAB, 2013)** study has shown urban, rural and overall diabetes prevalence in Tamil Nadu to be 13.7%, 7.8% and 10.4%, respectively, although prediabetes prevalence was low i.e. 9.8%, 7.1% and 8.3% in urban, rural and overall population.

A **survey conducted in Chennai (2013)**, reported that urban areas in India had a significantly higher incidence of diabetes. In India, overall census of hospital admission due to diabetes mellitus was 11.3% in Chennai, 9.4% in Delhi, 2.6% in Mumbai, 2.2% in Hubli, 4.2% in Hyderabad, Lucknow 2.03%, 1.7% in Jabalpur and 8.7% in Trivandrum. These figures shows that diabetes mellitus is more prevalent in affluent societies than in rural areas of South India.

In the **Chennai Urban Rural Epidemiology Study (CURES) 2013,** 17.6% patients were found to have Diabetic Retinopathy (DR), 26.9% had microalbuminuria and 26.1% had peripheral neuropathy. The study also demonstrated that 1 out of every 5 diabetic individual, may develop DR.

As per the **Chennai Urban Population Study (CUPS) 2013**, 21.4% had Coronary Artery Disease (CAD) and 6.3% had Peripheral Vascular Disease (PVD). Another study from South India found retinopathy (23.7%) and neuropathy (27.5%) amongst the most common complications of T2DM. Other complications in this study were Cardio Vascular Disease (CVD) 11.4%; PVD 4.0%; stroke 0.9% and hypertension (in 38% of patients). Foot infection and amputation rates were found to b`e higher among rural than in urban patients; (34 vs. 26%, $P = 0.0001$) and (8 vs. 3%, $P < 0.05$), respectively.

1.1 SIGNIFICANCE AND NEED FOR THE STUDY

Neuropathy pain is a well-known complication arising out of diabetes mellitus. It has a huge impact on a person's daily life both physically and mentally. The origin of pain may be in the peripheral nerves of central nervous system. Clients who are suffering from chronic diabetes mellitus will experience neuropathy pain as hyperglycaemia alters the physiology of peripheral nerves which results in neuropathy pain. Many alternative therapies were there to overcome diabetic neuropathy pain; one among them is contrast bath which has a significant effect in reducing the level of neuropathy pain.

Dan Ziegler MD conducted a **recent survey in Augsburg, Germany (2013)** and reported that polyneuropathy prevalence was 13.3% in diabetic subjects, 8.7% in individuals with impaired glucose tolerance, 4.2% in individuals with impaired fasting glucose, and 1.2% in individuals with normal glucose tolerance. Independent factors significantly associated with Diabetic Painful Neuropathy (DPN) were age, weight, and peripheral arterial disease and also conducted a **survey in U.K,(2013),** reported that majority (96%) of diabetic patients reported their neuropathic pain to their physician and received treatment. Treatment for pain was antidepressants in 43.5% of cases, anticonvulsants in 17.4%, opiates in 39%, and alternative treatments in 30%. Whereas 77% of the patients reported persistent pain over 5 years, 23% were pain free over at least 1 year. Concluded the survey that neuropathic pain persists in the majority of diabetic patients for many years.

Various non pharmacological treatments are available to reduce the level of neuropathy pain. This includes yoga, exercise, contrast bath, foot massage therapy, acupuncture and acupressure. In the **Journal of Diabetes and Prevention**, regular exercises can improve blood oxygen flow to muscles which in turn strengthens the muscles and helps to combat symptoms of neuropathy. Yoga postures are of a good deal to regain the loss of flexibility in neuropathy. Hence they concluded to avoid complications like diabetic neuropathy by practicing exercise and yoga and it should be inculcated in their daily routine.

Contrast bath, also known as alternate bath, allegedly promotes the cyclic vaso constriction and vasodilatation and enhances the reduction of neuropathy pain in clients with diabetes mellitus. Protocols may involve alternate immersion of lower extremities in warm water and cold water. Protocols may differ with respect to who performs the contrast bath and climatic changes in which it is performed. Professionals who may provide the service include nurses, occupational therapists and physical therapists. In some cases, family members and clients may be trained in the techniques and are given primary responsibility for providing the therapy. Treatment may be delivered in the hospital, nursing home or at patients home.

Contrast bath essentially acts as a "pump", allowing blood flow in to the area of inflammation and aiding in pushing the fluid into the blood stream / lymphatic system riding the area of toxins and buildup of metabolites. Warm therapy and cold therapy should be administered at 2minutes and 1 minute for 4 cycles to keep the foot free from neuropathy pain. **(Journal of Diabetes and Metabolic Disorders, 2014)**

Hydrotherapy or contrast bath can be administered for diabetes client with neuropathy pain. The feet was treated in hot water at 104 degrees F (40 degrees C) for 3-4 minutes followed by ice water or tap water at 45 to 70 degrees F. (7-21 degree C) for 30 seconds to 1 minute which results in the pain reduction. (**Contributed by the College of Health Evangelism Online School, 2014).**

Jessica Marsh (2014) conducted an experimental study to know the effectiveness of contrast bath among clients with sprains and strains in the ankle and foot at a massage centre, Halifax, Nova Scotia, Canada. The investigator did contrast bath alternatively using hot water with 36-38 degrees C (3minutes) and cold water with 4-21 degrees C(10 seconds to 1 minute) for 3 cycles, always ending with cold. The study result reported that there was a reduction in the level of pain in the ankle and foot.

Donna E. Breger Stanton et al (2012) conduced a systematic review among 28 clinical research articles on contrast bath from 1938 onwards in which 10 met the inclusive criteria set by the authors to know the effectiveness of contrast bath on diagnosis of rheumatoid arthritis and diabetes,to note the physiological temperature

variations on blood flow, temperature of subcutaneous muscles and intramuscles, the influence of room temperature, pain and age. Definitive conclusions were made that the contrast bath increases superficial blood flow and skin temperature in foot which inturn reduces the pain level.

Gormans J M et al (2011) conducted a quasi experimental study to assess the effectiveness of hydrotherapy among 20 diabetes mellitus clients with foot pain who were randomly selected, admitted in a medical ward. Foot immersion was done in hot water for 3 minutes and cold water for 30 seconds, alternating for 3 cycles. The study finding revealed that there was reduction in foot pain which was noticed by using numerical pain scale.

Linda Fehrs (2009) conducted an experimental study to assess the effectiveness of contrast bath on 20 diabetic neuropathy pain among diabetic clients attending a massage centre at US. Hot bath was administered at 100-115 degree and a cold bath in a range of 40-65 degrees for half an hour. The study result showed that there was reduction in pain level. The study was concluded that heat can help to relax aching while cold reduces inflammation and inhibits pain.

Nick Grantham (2008) conducted an experimental study to know the effectiveness of contrast bath among 60 clients with diabetic foot attending a foot clinic at China. They took 30 minutes for each client to provide the intervention. The temperature of the hot water was 35-40 degree C for 3-4 minutes and cold water was 10-15 degree C for 3-4 times. The study concluded that contrast bath stimulates the nervous system since brain receives and recognises various information(hot and cold),hence it reduces pain due to temperature variations.

In the diabetic outpatient department, clients with neuropathy pain are been treated with various pharmacological management. During the clinical experience in the neuropathy centre for DM, the researcher observed that taking analgesics(pain killer) has a greater impact on causing side effects to health. So the researcher developed an interest towards alleviating pain through various non- pharmacological treatment and was very particular in selecting a cost effective and easily accessible method of providing comfort

to the diabetic clients. This motivated the researcher to conduct the study on effectiveness of contrast bath on reducing the level of neuropathy pain among clients with diabetes mellitus, since it is done with water which is easily available to all clients.

1.3 STATEMENT OF THE PROBLEM

A study to assess the effectiveness of contrast bath on level of neuropathy pain among clients with diabetes mellitus attending diabetic outpatient department at selected hospital, Chennai.

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1.4 OBJECTIVES

1. To assess and compare the pre and post test level of neuropathy pain among the experimental and control group.
2. To compare the pre-test and post test level of neuropathy pain between the experimental and control group
3. To associate the selected demographic variables with mean differed level of neuropathy pain in the experimental and control group.

1.5 OPERATIONAL DEFINITIONS

1.5.1 Effectiveness

It refers to the outcome of contrast bath (warm bath and cold bath) on the level of neuropathy pain among diabetic clients which was assessed by using Galer Neuropathy Pain Scale.

1.5.2 Contrast Bath

It refers to the alternative immersion of the feet in warm water (100°-105° F) for 3 minutes and cold water (60°-70°F) for 1 minute alternatively which was repeated for 5 cycles with a total duration of 20 minutes.

1.5.3 Neuropathy Pain

It refers to the discomfort experienced in the feet of the client with diabetes mellitus manifested by sharpness, dullness, itching, overall unpleasantness which was assessed by using Galer Neuropathy Pain Scale.

1.5.4 Client With Diabetes Mellitus

It refers to the client medically diagnosed with type I or type II diabetes mellitus since >5 years , and having complaints of neuropathy pain and receiving treatment from the diabetic outpatient department in the selected setting.

1.6 ASSUMPTION

1. Clients with diabetes mellitus may have neuropathy pain.
2. Contrast bath may reduce the level of neuropathy pain in clients with diabetes mellitus.

1.7 NULL HYPOTHESES

NH_1- There is no significant difference between the pre-test and post-test level of neuropathy pain among the experimental and control group.

NH_2- There is no significant difference in the pre-test and post test level of neuropathy pain between the experimental and control group.

NH_3- There is no significant association of the selected demographic variables of mean differed level of neuropathy pain in experimental and control group.

1.8 DELIMITATION

The study was delimited to a period of 4 weeks

1.9 CONCEPTUAL FRAMEWORK

A conceptual framework or a model is made up of concepts, which are the mental images of the phenomenon. It provides the guidelines to proceed to attain the objectives of the study based on a theory. It is a schematic representation of the steps, activities and outcomes of the study.

The investigator adopted **WIEDENBACH'S HELPING ART OF CLINICAL NURSING THEORY** as a basis for the conceptual framework, which was aimed to assess the effectiveness of contrast bath on level of neuropathy pain among clients with diabetes mellitus in an outpatient department at selected hospital, Chennai.

Ernestine Wiedenbach's enrolled in the John Hopkins School of nursing and wrote Family Centered Nursing and developed the helping art of clinical nursing perspective theory in 1964. According to this theory, the practice of nursing comprises a wide variety of services, each directed towards the attainment of one its three components.

STEP – 1: IDENTIFYING THE NEED FOR HELP

The Nurse investigator perceives the patient behavior as consistent or inconsistent with the nurse's concept of comfort or capability. In identifying the need, the nurse investigator perceives nurse's ability to care for the clients with diabetic neuropathy pain in outpatient department at Sir Ivan Stedeford Hospital.

There are two components in identifying the need for help.

a) General Information:

This comprises of collection of demographic variables and pre test level of neuropathy pain.

b) The Central Purpose:

Central purpose refers to what the nurse investigator want to accomplish. Here the central purpose was to reduce the level of neuropathy pain among clients with diabetes mellitus attending outpatient department.

STEP – II: MINISTERING THE NEEDED HELP

The Nurse investigator formulates a plan for meeting the patient's need for help based on available resources.

a) Prescription

It refers to the plan of care, the nature of action that will fulfill the central purpose. Here, the prescription was the contrast bath which reduces the level of neuropathy pain among clients with diabetes mellitus.

b) Ministering (intervention)

In this study the nurse investigator utilizes the following intervention to reduce the level of neuropathy pain among clients with diabetes mellitus.

Contrast Bath:

It refers to an alternate immersion of feet in warm water (100°-105° F) for 3 minutes and cold water (60°-70°F) for 1 minute.

The investigator does contrast bath for 5cycles with a total duration of 20 minutes.

c) Realities

The realities are the immediate situation that influences the fulfilment of the central purposes. Nurse investigator should consider the realities of the situation in which she has to provide nursing care. Wiedenbach's defines the realities as:

1. The Agent:

Refers to a person who is providing care to the delegates characterized by personal attribute, problems, commitment and competence in nursing. Here it was the nurse investigator, who directed all action/prescription towards the central purpose.

2. The Recipient:

It refers to the client who is characterized by the personal attributes, problems, capacities, aspirations and ability to cope with the concern or problems being experienced. Here it was the clients with diabetes mellitus attending the diabetic outpatient department at Sir Ivan Stedeford hospital who received the nurse investigator's action/prescription.

3. The Goal:

It refers to the outcome of the nurse investigator who wishes to achieve. Here it was to reduce the level of neuropathy pain.

4. The Means:

Comprises the activities and devices through which the agent attains the goal. The means include skills, techniques, procedures and devices that may be used to facilitate nursing practice. Here it was the contrast bath for 20 minutes (5 cycles) to reduce the level of neuropathy pain.

5. The Framework:

Refers to the facilities in which nursing is practiced. Here it was the diabetic outpatient department at Sir Ivan Stedeford Hospital, Chennai. It is a 250 bedded multispecialty hospital, with approximately 350 diabetic clients attending the diabetic outpatient department every day.

STEP – III: VALIDATING THE NEEDED HELP WAS MET

It refers to a collection of evidence that shows if the client's need has been met and that his functional ability has been restored as a direct result of the nurse's action. This step involves the post test assessment after ministering the help and the comparison/analysis to infer the outcome. This approach there by enabled the researcher to make suitable decision and recommended action to continue, drop or modify the nursing action.

The expected outcome of selected nursing intervention was to reduce the level of neuropathy pain by the researcher, where the level of pain comprises of mild, moderate and severe pain.

- Reassessment**-** If there was no reduction in the level of neuropathy pain after providing contrast bath the researcher recommended for reinforcement.
- Enhancement**-** If there was reduction in the level of neuropathy pain after providing contrast bath , enhancement of the intervention was encouraged.

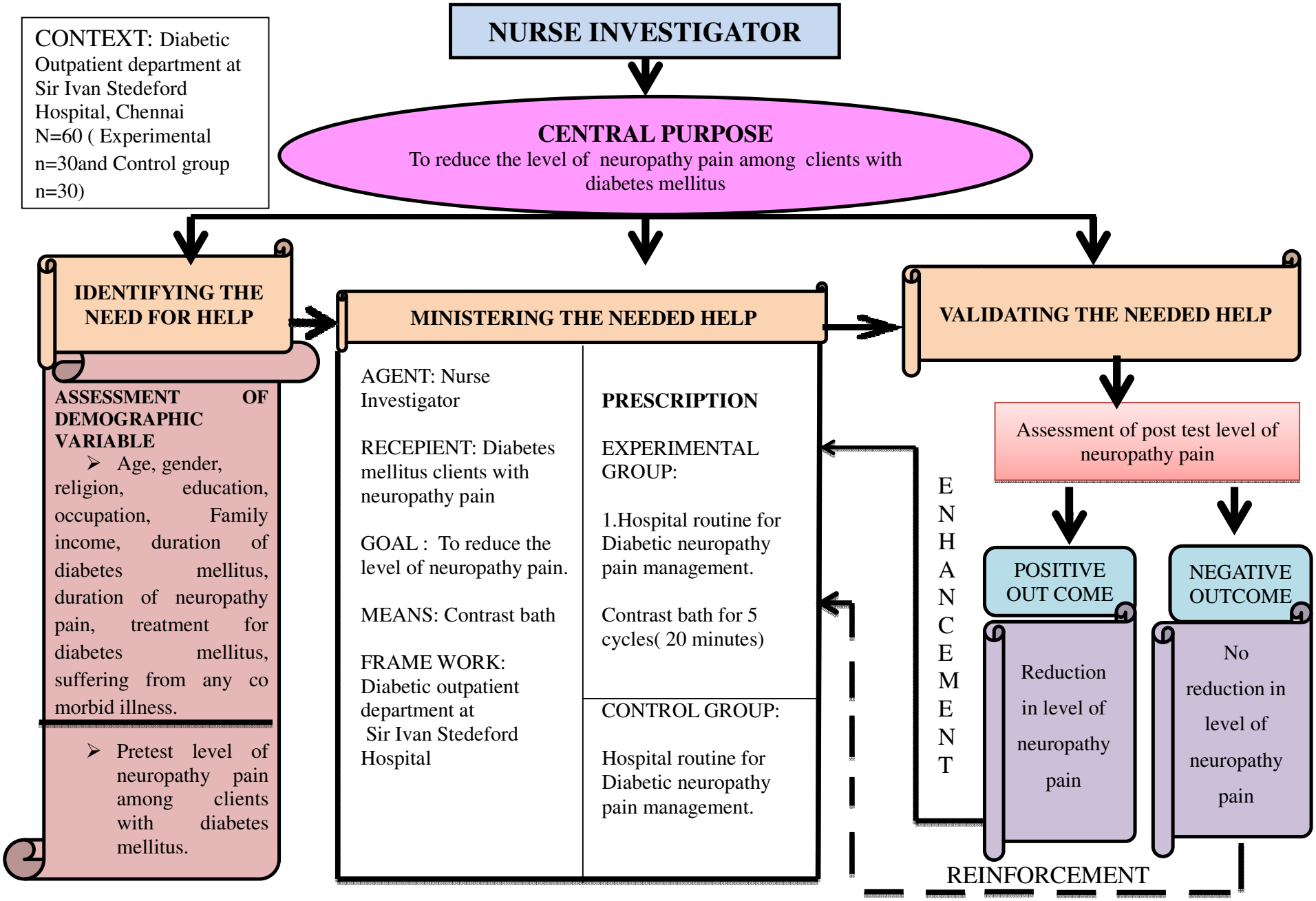


Fig 1.9.1: CONCEPTUAL FRAMEWORK BASED ON WIEDENBACH'S HELPING ART OF CLINICAL NURSING THEORY

1.10 OUTLINE OF THE REPORT

Chapter 1: Dealt with introduction, background of the study, need for the study, statement of the problem, objectives, operational definitions, assumptions, null hypotheses, delimitation and conceptual framework.

Chapter 2: Contains the scientific review of literature related to the present study.

Chapter 3: Presents the methodology of the study and plan for data analysis.

Chapter 4: Focuses on data analysis and interpretation.

Chapter 5: Enumerates the discussion and findings of the study.

Chapter 6: Consist of summary, conclusion, implications, recommendations and limitations of the study.

The study report ends with selected Reference and Appendices.

REVIEW OF LITERATURE

Polit and Beck (2008), stated that review of literature is a systematic search of a published work to gain information about a research topic. The literature review, not only involves searching, surveying and evaluation of the relevant literature but also describing, synthesizing and assimilating the information into a summary, critically analyzing the facts gathered methodologically to identify areas of controversy and formulate questions for further research, and presenting it in a discursive organized prose.

An extensive review of literature was done by the investigator to lay a broad foundation for the study.

SECTION 2.1: Scientific reviews related to diabetes and neuropathy pain
SECTION 2.2: Scientific reviews related to contrast bath
SECTION 2.3: Scientific reviews related to contrast bath on level of neuropathy pain among clients with diabetes mellitus

SECTION 2.1: REVIEWS RELATED TO DIABETES AND NEUROPATHY PAIN

Fernando D J (2014), conducted a descriptive study to determine the prevalence of diabetic neuropathy and ulceration due to neuropathy among 500 clients with type 2 DM attending a Sri Lankan diabetic clinic who were randomly selected and assessed for diabetic neuropathy by using neuropathy system score (NSS), neurological disability score (NDS) and pressure perception threshold using Semmes Weinstein monofilaments. The result depicted that clients with neuropathy were elder (mean 55.69 years SD 14.16) than the clients who did not (mean 47.1 years, SD 15.05 p = 0.001) and had diabetes for a longer period (mean 7.5, SD 8 years vs 4.8 SD 5.66, p = 0.002).123 of clients had neuropathy according to the criteria used. The study revealed that ulceration due to neuropathy is a significant cause of morbidity in clients with type 2 DM and foot care programmes should be conducted at all diabetic clinics in Sri Lanka.

Arsalan Cheema et al (2014) conducted a population–based study using WHO diagnostic criteria among 151 age specific prevalence estimates obtained from 39 studies. Prevalence of DM was estimated to be 7.47% for 2005 and 7.60% for 2010. Prevalence was strongly associated with increased age, male gender and urban residency ($P < 0.001$). The study result concluded that diabetes prevalence in Southern Asia is high and predicted to increase in the future as life expectancy rises and the region continues to urbanise.

Barrett AM et al, **(2014)** conducted a descriptive study to examine the epidemiology, public burden, and treatment of diabetic peripheral neuropathic pain using a comprehensive computerized literature review resulted in 321 articles. Several epidemiological studies were assessed for diabetic peripheral neuropathy among clients with DM and reported prevalence rates of 26-47%. No estimates of DPNP prevalence were reported, although one study (N = 2,405) reported that 26.8% of participants with diabetes experienced either pain or tingling sensation in the foot.

Won JC et al (2014) conducted a descriptive study to assess the prevalence of neuropathy in Korea. They found neuropathy is the most common complication associated with DM. Diabetic neuropathy can be presented with loss of sensation, which leads to neuropathic ulcers and finally ends in amputation.

Garrow AP et al (2014) conducted a single- blind , placebo controlled RCT to rule out the acupuncture treatment for diabetic painful neuropathy among 45 clients. The study was carried out for 10 weeks in which each lower leg were treated with 5 standardised acupuncture points. Clients outcome was measured with Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) scale, lower limb pain (Visual Analogue Scale, VAS); Sleep Problem Scale (SPS); Measure Yourself Medical Outcome Profile (MYMOP); 36-item Short Form 36 Health Survey and resting blood pressure (BP). The study result showed that there is an effective pain relief without any side effects.

Padmajakumari Rani et al (2013) conducted a population based sample of 1401 persons with diabetes to assess the neuropathy who underwent Vibration perception threshold (VPT) measurements (cut off $\geq$ 20 V). Severity was categorized in 3 levels based on VPT score as mild (20-24.99 V), moderate (25-38.99 V), and severe ($\geq$39 V).

Overall prevalence rate was 18.84% where as mild was 5.9% , moderate was 7.9%, and severe was 5% . For all 3 levels of neuropathy, increase in age/ year was the risk factor which showed statistically significant at p<0.001. For severe diabetic neuropathy, other significant risk factors were duration of diabetes mellitus ($P = 0.027$). The study result suggested that every fifth individual in a population of type 2 diabetes is likely to have diabetic neuropathy.13 % of moderate and severe level of neuropathy will leads to complications like foot ulceration or lower limb amputation in vulnerable group.

Kiani J et al (2013) conducted a cross sectional study among diabetic clients who reside in Hamedan, Iran to know the prevalence of diabetic peripheral neuropathy (DPN) and its associated risk factors. For the diagnosis of diabetic neuropathy, Standard Neuropathy Symptom Score (NSS) and Neuropathy Disability Score (NDS) criteria was used. The overall prevalence of DPN was 45.7%. In type 1 diabetic clients 21.5%, and in type 2 DM 49.3% of prevalence was noted at ($P < 0.001$). Duration of diabetes and education level were significantly associated with DPN in type 1 diabetic clients and a history of foot ulcer, age, duration of diabetes, weight, education level, and sex had a significant association with DPN in type 2 diabetic clients. The study concluded that there was a relatively high prevalence of DPN among diabetic population and a significant difference existed between types 1 and 2 diabetic clients.

Viswanathan, V (2013) conducted a descriptive study on diabetic foot complications. Across India, from 4 different centres, 1319 type II diabetic clients were selected. The study result depicted that prevalence of neuropathy was 15%(n=193) and PVD was 5%(n=60). 7.6% clients were presented with infections and 3% of subjects had undergone major amputation. The study concluded that neuropathy (15%) was found to be a major risk factor for diabetic foot infections.

Erbas T et al (2013) conducted a multicenter cross-sectional study among clients with diabetes mellitus attending university outpatient clinic, Turkey, to determine the prevalence of diabetic neuropathic pain. Neurologic examinations and nerve conduction studies along with clinical diabetic neuropathy score, Galer Neuropathy pain scale and Signs pain scale were performed over 1,113 clients (46.2% male) from 14 centers. Neuropathy pain 14% and diabetic peripheral neuropathy 40.4% were observed. The

study concluded that early detection and clinical examinations were important for diagnosis of DPN and neuropathy pain.

M.A. Wijesuriya, et al (2010) conducted a retrospective analytical study to assess the chronic complications of type 2 diabetes with the biochemical and physical estimations in subjects attending single visit screening for complications. The clinical records of the clients with type 2 diabetes who attended the National Diabetes Centre of Sri Lanka were received from January 2005 to December 2010. A total of 12,517 type 2 diabetic clients (aged 20 years or above) were included in the study in which 7102 (56.7%) were present with microvascular complications, 2654 (21.2%) had retinopathy, 3509 (28%) had neuropathy and 4173 (33.3%) with nephropathy.

Morkrid K. et al (2010) carried out a descriptive study to estimate the prevalence and risk factors for diabetic peripheral neuropathy (DPN) among 294 type 2 diabetic clients who were randomly selected and diagnosed for 5-11 years, attending the diabetic outpatient department at BIRDEM hospital, Bangladesh. Clients Neuropathy Symptom Score (NSS) and Neuropathy Disability Score (NDS) was assessed for DPN. Demographic variables, anthropometric measurements, blood pressure, waist and hip circumference, and random blood and urine samples were collected. The study findings revealed that overall DPN prevalence was 19.7 %. Age and duration of diabetes was associated with prevalence.

Lu B et al (2010) conducted a descriptive study among 435 Chinese clients diagnosed with type 2 diabetes at shanghai downtown to assess the prevalence of diabetic peripheral neuropathy (DPN) and associated risk factors. Clients BMI, resting blood pressure, complete foot examination, fasting blood measures, urinary albumin-to-creatinine were carried out for clients aged over 30 years. The study results depicted that prevalence of DPN was 61.8%.

Lavery, LA., et al (2010) conducted a descriptive study, to identify causes and factors associated for foot ulcers, among 103 clients with recently healed foot ulcer in USA. A cluster analysis found pathways accounted for 64.1% of cases. They were namely neuropathy, peripheral vascular disease, penetrating trauma, ill fitting footwear.

The study results suggested that if the causes were identified and addressed with appropriate intervention, risk of ulceration and amputation can be reduced.

SECTION 2.2: SCIENTIFIC REVIEWS RELATED TO CONTRAST BATH

Janseen RG et., al (2014) conducted a randomized controlled study of contrast baths on Carpel Tunnel Syndrome clients in hand clinics, Russia . Data were gathered from 58 clients before and 56 clients after Carpal Tunnel Release surgery. Randomly clients were assigned to three treatment group protocols—contrast baths with exercise, contrastbaths without exercise, and an exercise only group. Pre and post operatively hand volumetry, before and after treatment was done. Although all three treatments resulted in a slight increase in hand volume both pre- and post surgery. The ANOVA for postsurgery difference among treatment group had F=0.544 (2 and 53 df), p=0.584.The study concluded that the use of contrastbath was effective in hand volumetry values among clients with carpel tunnel syndrome.

Higgins T et al (2012) conducted an experimental study to evaluate hydrotherapy as recovery strategy for simulated game of rugby union among 24 male players who were randomly divided into 3groups (8 in each group). One group received cold water(10 degree C for 5 minutes) immersion therapy for 2 times. Second group received contrastbath therapy (hot 38 degree C and cold 10 degree C for 5 cycles) and the third group received passive recovery. Three training session was carried out. The study results indicated that cold water immersion therapy and contrasts baths was effective to athlete's recovery from team sport than passive recovery for rugby union.

Shih CY et al (2012) conducted an experimental study to explore the effect of heat to cold on brachial artery mean blood velocity(aMBV) during contrast bath among 34 young healthy volunteers . Each participant underwent 2 seperate sessions of contrastbaths. First the participants immersed their hands in hot water (40°C) for 3 minutes and then cold water (18°C) for 1 minute repeated for 3 cycles. Secondly participants immersed their hands in hot water (40°C) for 10 minute. A color Doppler ultrasound scanner was used to measure aMBV, The study result concluded that the longer duration in the second heating phase during contrast baths was required to produce a sufficient fluctuation in blood flow.

French DN et al (2011) conducted an experimental study to assess the effect of contrast bathing on exercise-induced muscle damage (EIMD) among 26 young men who underwent muscle soreness, serum creatine kinase (CK) and myoglobin (Mb), joint range of motion, limb girth, counter movement jump (CMJ) and resistance exercise challenge (REC) to induce EIMD. After the REC, subjects were separated into 2 groups: experimental group who had contrast bath and control group with routine management. Forty-eight hours after REC, the subjects exercise performance was reassessed. The study results revealed that the contrast bathing may transiently attenuate postexercise soreness.

Petrofsky J, et., al (2010) conducted an experimental study among 14 people with type 2 DM compared with age matched controls to determine the skin blood flow on the dorsal and plantar foot with contrast bath. For the experimental group 3 minutes warm bath and 1 minute cold bath and 6 minutes warm and 2 minutes of cold bath was administered. For control group, 3 minutes warm to 1 minute cold bath was administered which elicited significantly ($p < 0.01$) greater blood flow(BF) than placing the limb continuously in warm water or using a 6:2 ratio of warm to cold bath time. In control group, there was also a greater plantar than dorsal blood flow. The study findings revealed that the BF response to contrast bath temperatures may be a good diagnostic test for diabetic vascular impairment.

Sorokina EL et al (2001), conducted an experimental study to know the effect of contrastbaths on the hemostatic function of 72 clients with ischemic heart disease(post infarction cardiosclerosis and stable angina pectoris). Hydrotherapy with contrast bath was administered for the clients. Hemostasis was assessed by recalcification time, blood plasma tolerance to heparin, fibrinolytic activity, functional activity of anti thrombin, soluble fibrin-monomeric complex, platelet count and aggregation before and after the intervention. Hydrotherapy contrastbaths was hemostatically effective in 70.9% of clients. The result revealed that the hydrotherapy had beneficial effects on coagulation status of the clients.

Rychkova MA et al, **(2000)** conducted an experimental study to know the effectiveness of contrast bath in the rehabilitation of clients with chronic bronchitis in Russia. 91 patients with chronic bronchitis with obstructive syndrome were treated with

contrastbaths. The latter produced good results in 80.3% of the clients. This treatment was analysed as to clinical efficacy, the effect on the external respiration, right heart hemodynamics, inflammation activity, changes in immunity system. Study report reveals that the contrastbaths can be advocated in chronic bronchitis clients after treatment.

Ushakova OE et al (2000) conducted an experimental study in Russia to assess the effect of contrast bath on central nervous system function in 26 female clients with a disordered menstrual function suffering from neuroendocrine syndrome with dysmenorrhea were performed with Electro Encephalo Graphy (EEG), REG and with psychoemotional tests. The findings were indicative of defects in cerebral function and circulation. This confirms contribution of the central nervous system to the onset of their disease. They underwent contrast therapy with hot and cold water for 5 cycles for a duration of 30 minutes. The treatment resulted in recovery of mechanisms of cerebral regulation as seen from attenuation of clinical symptoms, positive changes in psychoemotional status, EEG and REG.

SECTION 2.3: SCIENTIFIC REVIEWS RELATED TO CONTRAST BATH ON LEVEL OF NEUROPATHY PAIN AMONG CLIENTS WITH DIABETES MELLITUS

Contrast bath essentially acts as a "pump", allowing blood flow in to the area of inflammation and aiding in pushing the fluid into the blood stream / lymphatic system riding the area of toxins and buildup of metabolites. Warm therapy and cold therapy should be administered at 2minutes and 1 minute for 4 cycles to keep the foot free from neuropathy pain. **(Journal of diabetes and metabolic disorders, 2014)**

Hydrotherapy or Contrast bath can be administered for diabetes client with neuropathy pain. The body part(s) to be treated in hot water at 104 degrees F (40 degrees C) for 3-4 minutes followed by ice water or tap water at 45 to 70 degrees F. (7-21C) for 30 seconds to 1 minute which results in the reduction of neuropathy pain. (**Contributed by the College of Health Evangelism Online School, 2014).**

Jessica Marsh (2014) conducted an experimental study to know the effectiveness of contrast bath among clients with sprains and strains in the ankle and foot at a massage centre, Halifax, Canada. Investigator did contrast bath alternatively using hot

water with 36-38 degrees C(3minutes) and cold water with 4-21 degrees C(10 seconds to 1 minute) for 3 cycles, always ending with cold. The study result reported that there was a reduction in the level of pain in the ankle and foot.

Donna E. Breger Stanton et al (2012) conduced a systematic review among 28 clinical research articles on contrast bath from 1938 onwards in which 10 met the inclusive criteria set by the authors to know the effectiveness of contrast bath on diagnosis of rheumatoid arthritis and diabetes ,to address the physiological changes of hot and cold on blood flow, intramuscular temperature, subcutaneous temperature, the influence of room temperature , pain and age. The definitive conclusions was made that the contrast bath increases superficial blood flow and skin temperature in foot which relieves pain.

Gormans JM et al (2011) conducted a quasi experimental study to assess the effectiveness of hydrotherapy among 20 diabetes mellitus clients with foot pain who were admitted in a medical ward who were randomly selected. Foot immersion was done in hot water for 3 minutes and cold water for 30 seconds, alternating for 3 cycles. The study finding revealed that there was reduction in foot pain which was noticed by using numerical pain scale.

Linda Fehrs (2009) conducted an experimental study to assess the effectiveness of contrast bath on 20 diabetic neuropathy pain among diabetic clients attending a massage centre at US. Hot bath was administered at 100-115 degree and a cold bath in a range of 40-65 degrees for half an hour. The study result showed that there was reduction in pain level. The study was concluded that heat can help to relax aching while cold reduces inflammation and inhibits pain.

Nick Grantham (2008) conducted an experimental study to know the effectiveness of contrast bath among 60 clients with diabetic foot attending a foot clinic at China. They took 30 minutes for each client to provide the intervention. The temperature of the hot water was 35-40 degree C for 3-4 minutes and cold water was 10-15 degree C for 3-4 times. The study concluded that contrast bath stimulates the nervous system since brain receives and recognises two different types of information(hot and cold), and the changes in temperature may also help in reducing the pain.

RESEARCH METHODOLOGY

Methodology of research organizes all the components of study in a way that most likely will lead to valid answers for the problems that have been posted. **(Burns and Groove, 2008).**

This chapter deals with the methodology adopted for the study. It includes the research approach, research design, variables, setting, population, sample, and criteria for selection of the sample, sample size, sampling technique, development and description of the tool, content validity, pilot study, and reliability of the tool, data collection procedure and plan for data analysis.

3.1 RESEARCH APPROACH

Quantitative research approach was used in this study.

3.2 RESEARCH DESIGN

The research design used in this study was Experimental- between group pre test- post test design.

The schematic representation follows

Group	**Pre test (O_1)**	**Intervention (X)**	**Post test (O_2) (same day of intervention)**
Experimental group	Assessment of level of neuropathy pain among diabetic clients using Galer Neuropathy Pain Scale.	1.Routine hospital care 2. Contrast bath (warm bath and cold bath alternatively repeated for 5 cycles with a total duration of 20 minutes).	Assessment of level of neuropathy pain among diabetic clients using Galer Neuropathy Pain Scale after 5-10 minutes.
Control group	Assessment of level of neuropathy pain among diabetic clients using Galer Neuropathy Pain Scale.	Routine hospital management of neuropathy pain.	Assessment of level of neuropathy pain among diabetic clients using Galer Neuropathy Pain Scale.

3.3 VARIABLES

3.3.1 Independent Variable

Contrast bath (warm and cold bath).

3.3.2 Dependent Variable

Level of neuropathy pain.

3.3.3 Extraneous Variable

Age, gender, religion, education, occupation, income, type of family, extent of family support, duration of illness, level of pain tolerance, treatment for diabetes mellitus, co morbid illness.

3.4 SETTING

The research setting was diabetic outpatient department at Sir Ivan Stedeford Hospital, Chennai. It is a 250 bedded multispecialty hospital, with approximately 350 diabetic clients attending the diabetic outpatient department every day. The diabetic outpatient department functions from Monday to Saturday between 8am -1 pm, with the support of 5 diabetologist. Round the clock inpatient services are provided to the diabetic clients.

3.5 POPULATION

3.5.1 Target Population

All the clients who are suffering from neuropathy pain due to diabetes mellitus.

3.5.2 Accessible Population

All the clients who are diagnosed with diabetes mellitus with neuropathy pain and attending the diabetic outpatient department at Sir Ivan Stedeford Hospital, Ambattur, Chennai.

3.6 SAMPLE

The clients who satisfied the inclusion criteria were the samples of the study.

3.7 SAMPLE SIZE

60 clients with diabetes mellitus who fulfill the inclusive criteria with 30 each in experimental and control group.

3.8 CRITERIA FOR SAMPLE SELECTION

3.8.1 Inclusion Criteria

1. Clients aged 18 years and above.
2. Clients with diabetes mellitus with 5 years of chronicity.
3. Clients with diabetes mellitus having neuropathy pain attending the diabetic outpatient department.
4. Clients who are willing to participate in the study.
5. Clients who can understand Tamil or English

3.8.2 Exclusion Criteria

1. Clients who have swelling in their leg, foot ulcers or gangrene.
2. Client who have intolerance to cold/warm temperature.
3. Clients with severe visual/hearing impairment.
4. Client on pain medications
5. Client using special footwear.
6. Client with loss of sensation in the foot.

3.9 SAMPLING TECHNIQUE

The samples were selected by simple random sampling technique using lottery method. The investigator allocated the samples who took chit number 1 to the experimental group and the samples who took chit number 2 to the control group. Likewise the investigator selected 60 samples, 30 each in the experimental and control group.

3.10 DEVELOPMENT AND DESCRIPTION OF THE TOOL

After an extensive review of literature, discussion with the experts and with the investigator's professional experience, Galer Neuropathy pain scale was adopted..

The tool for the study had two parts:

3.10.1 PART A: DATA COLLECTION TOOL

This consisted of 2 sections

Section A: Assessment of demographic variables

Demographic variables include age in years, gender, religion, educational status, occupation, family income, duration of diabetes mellitus and neuropathy pain, treatment for diabetes mellitus, suffering from any co morbid illness.

Section B: Assessment of neuropathy pain using "Galer Neuropathy Pain scale"

Assessment was done before and after intervention.

ITEM	COMPONENTS	SCORE
1.Intensity of pain	No pain to The most intense pain sensation imaginable	0 to 10
2. Sharpness of pain	Not sharp to The most sharp sensation imaginable(like a knife)	0 to 10
3.Level of heat	Not hot to The most hot sensation imaginable(on fire)	0 to 10
4.Dullness	Not dull to The most dull sensation imaginable	0 to 10
5.Coldness	Not cold to The most cold sensation imaginable(freezing)	0 to 10
6.Skin integrity	Not sensitive to The most sensitive sensation imaginable(raw skin)	0 to 10
7.Level of itching	Not itchy to The most itch sensation imaginable like a mosquito bite	0 to 10

ITEM	COMPONENTS	SCORE
8.Quality of pain	Background pain to Single type pain all the time or only sometimes	0 to 10
9.Overall unpleasantness	Not unpleasant to The most unpleasant sensation imaginable(intolerable)	0 to 10
10. Intensity of deep and surface	No intensity of deep and surface to The most intense deep and surface pain sensation imaginable	0 to 10

Total score: 100

Scoring:

Total score is 100. The score is graded as follows:

- ≤ 50 - Mild neuropathy pain
- 51-75 - Moderate neuropathy pain
- >75 - Severe neuropathy pain

3.10.2 PART B: INTERVENTION PROTOCOL:

CONTRAST BATH:

It refers to an alternate immersion of the feet in warm water and cold water.

A) WARM BATH:

The feet is immersed in warm water for 3 minutes at a temperature of 100°-105°F.

B) COLD BATH:

Feet is immersed in cold water for 1 minute at a temperature of 60°-70°F.

The investigator did contrast bath by alternate immersion of client's feet in warm water for 3minutes followed by cold water for 1 minute and repeated this for 5 cycles with a total duration of 20 minutes.

3.11 CONTENT VALIDITY

The content validity of the data collection tool and intervention protocol was ascertained from the expert's opinion in the following field of expertise

- Neurologist-1
- Diabetologist -1
- Nursing expert-4

Modifications suggested by the experts in the tool such as duration of neuropathy pain and treatment for diabetes mellitus were related to the demographic variables and inclusive criteria which were incorporated in the tool. All the experts had their consensus and then the tool was finalized.

3.12. ETHICAL CONSIDERATION

The study was approved by **Institutional Ethical Review Board (IERB)** held on February 2013 by **ICCR,** Omayal Achi College of Nursing.

Ethics is a system of moral values that is concerned with the degree to which the research procedures adhere to the professional, legal and social obligations of the study samples. **Polit and Hungler (2011)**

1) BENEFICIENCE

The investigator followed the fundamental ethical principle of beneficence by adhering to

a) The right to freedom from harm and discomfort

The study was beneficial for the participants as it reduce neuropathy pain and prevents from chronic deformity.

b) The right to protection from exploitation

The investigator explained the procedure and nature of the study to the clients and ensured that the participants in both experimental and control group will not be exploited or denied from fair treatment.

2) RESPECT FOR HUMAN DIGNITY

The investigator followed the second ethical principle of respect for human dignity. It includes the right to self determination and the right to self disclosure

a) The right to self-determination

The investigator provided full freedom to the participants to decide voluntarily whether to participate in the study or to withdraw from the study and the right to ask questions.

b) The right to full disclosure

The researcher has fully described the nature of the study, the person's right to refuse participation and the researcher's responsibilities based on which both oral and written informed consent was obtained from the participants.

3) JUSTICE

The researcher adhered to the third ethical principle of justice; it includes participant's right to fair treatment and right to privacy

a) Right to fair treatment

The researcher selected the study participants based on the research requirements. The investigator followed hospital routine for control group. The contrast bath was given for the control group after the completion of post-test.

b) Right to privacy

The researcher maintained the participant's privacy throughout the study by not disclosing the purpose of intervention and details of the subject to other clients.

4) CONFIDENTIALITY

The researcher maintained confidentiality of the data provided by the study participants. The collected data was not disclosed to any other persons.

3.13 RELIABILITY

The reliability of the tool was established by test-retest method to assess the effectiveness of contrast bath. The reliability score was r=0.8.The 'r' value indicated the highly positive correlation, which showed that the tool is highly reliable, feasible and practicable to conduct the main study.

3.14 PILOT STUDY PROCEDURE

Pilot study was conducted at Sir Ivan Stedeford Hospital at Ambattur. A formal and written permission was sought from the Principal, Omayal Achi College Of Nursing, Medical Director and Nursing superintendent of the hospital.

A total of 10 diabetic neuropathy clients who fulfilled the inclusive criteria for sample selection were selected using simple random sampling technique by lottery method. After obtaining written consent from participants, data collection was commenced.

A brief explanation on the purpose of the study was given to the clients and a need assessment for contrast bath was done for all the clients after eliciting demographic details.

Pretest level of neuropathy pain was assessed using Galer neuropathy pain scale. Hospital routine was carried out for both experimental group and control group .For the experimental group the investigator carried out the contrast bath for a total duration of 20 minutes for each client. Post test level of neuropathy pain was assessed for both the groups using Galer neuropathy pain scale.

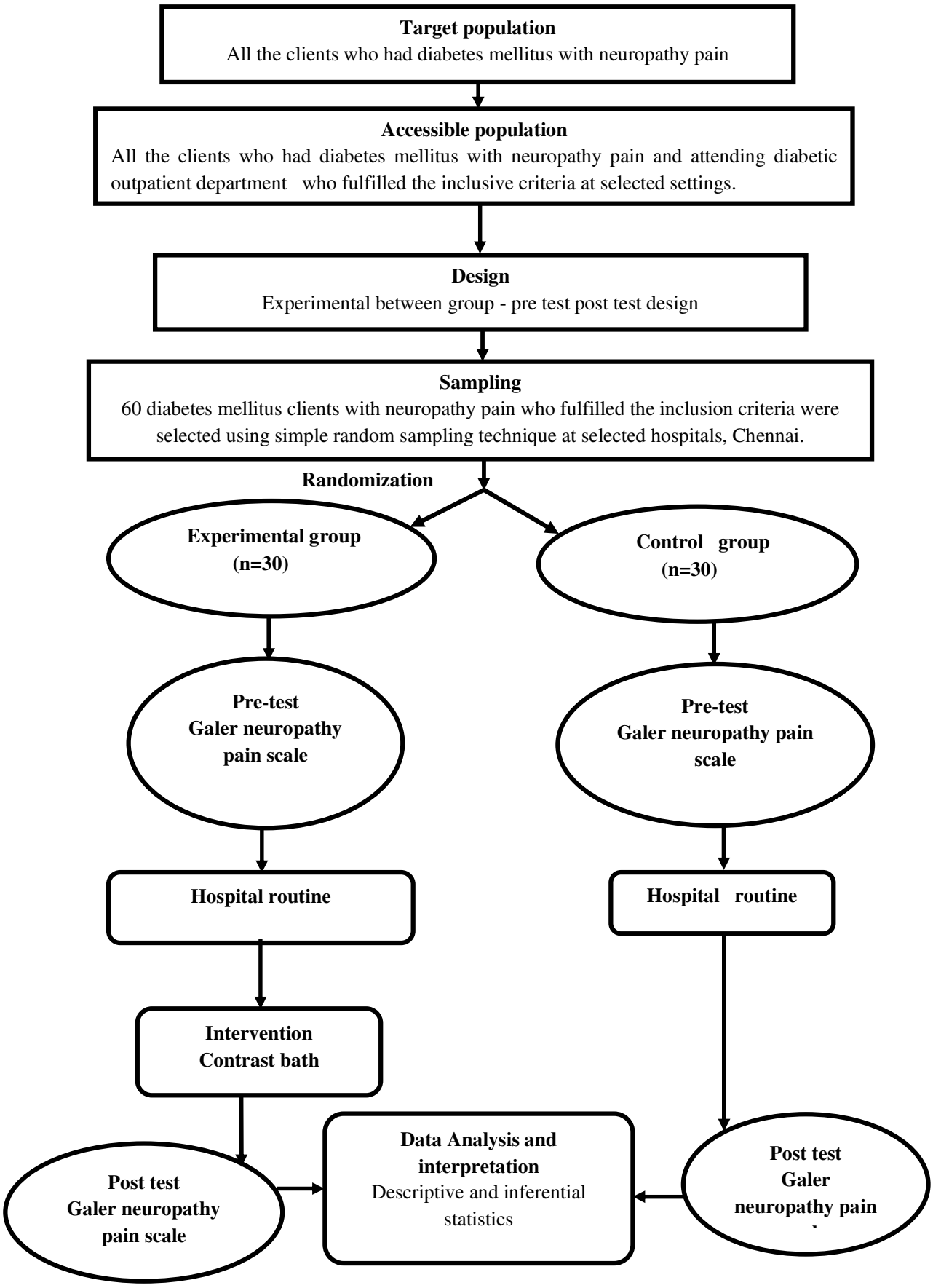
The analysis of the pilot study revealed that the‘t’ value to determine the effectiveness of contrast bath was ‘-8.3’, which showed high statistical significance at $p<0.05$ level. The result of the pilot study gave the evidence that the tool and contrast bath was reliable, feasible and practicable to conduct the main study.

3.15 PROCEDURE FOR DATA COLLECTION

The clients who were diagnosed to have diabetic neuropathy pain were gathered and seated in a well ventilated room. A brief introduction of self and explanation of the purpose of the study was given. The clients were allotted into experimental and control group using simple random sampling technique by lottery method. At first demographic details were obtained through questionnaire for 5 minutes. It took10 minutes to assess the pretest level of neuropathy pain using Galer neuropathy pain scale. The researcher faced difficulty in explaining the components of the pain scale in the regional language. The control group were underwent the hospital routine whereas the experimental group

were subjected to the contrast bath in addition to hospital routine. Clients in the experimental group were taken into the treatment room one by one for the contrast bath. The investigator used 2 basins with water (one for hot water and one for cold water). The temperature of hot water was 100-105 degree F and for cold water 60-70 degree F. the clients foot was immersed fully in hot water basin for 3 minutes followed by cold water basin for 1 minute. Then it was repeated for 5 times with the total duration of 20 minutes. The temperature of the water was maintained constant throughout the procedure by frequently adding hot or cold water. Immediately after the intervention, within 5-10 minutes, post test level of neuropathy pain was assessed using Galer neuropathy pain scale which took 5 minutes. The clients in the control group were asked to report to the diabetic outpatient department after hospital routine for assessing post test level of neuropathy pain using Galer neuropathy pain scale. It took 5 minutes for each person. Then the clients were taught about contrast bath and were encouraged to practice it frequently at home.

SCHEMATIC REPRESENTATION OF RESEARCH METHODOLOGY



3.16 PLAN FOR DATA ANALYSIS

The data obtained was analyzed by using both descriptive and inferential statistics.

3.16.1 Descriptive Statistics

1. Frequency and percentage distribution to analyse demographic variables of the experimental and control group.
2. Mean and standard deviation to analyze pre test and post test level of neuropathy pain among the experimental and control group.

3.16.2 Inferential Statistics

1. Paired ‘t’ test to compare the pre test and post test level of neuropathy pain among the experimental and control group.
2. Unpaired ‘t’ test to compare the pre test and post test level of neuropathy pain level between experimental and control group.
3. One way ANOVA to associate selected demographic variables of mean differed level of neuropathy pain in experimental and control group.

DATA ANALYSIS AND INTERPRETATION

The analysis is a process of organizing and synthesizing the data in such a way that the research question can be answered and hypotheses are tested **(Polit and Hungler, 2011).**

This chapter deals with the analysis and interpretation of the data to study the effectiveness of contrast bath on neuropathy pain among clients with diabetes mellitus in outpatient department at selected hospital, Chennai. The data was organized, tabulated and analyzed according to the objectives. The findings based on the descriptive and inferential statistical analysis, are presented under the following sections.

ORGANIZATION OF THE DATA

SECTION 4.1: Description of the demographic variables of the clients

SECTION 4.2: Assessment of pre-test and post-test level of neuropathy pain among clients with diabetes mellitus in the experimental and control group.

SECTION 4.3: Comparison of pre test and post test level of neuropathy pain among clients with diabetes mellitus in the experimental and control group.

SECTION 4.4: Association of selected demographic variables with the mean differed level of neuropathy pain score in the experimental and control group.

SECTION 4.1: DESCRIPTION OF THE DEMOGRAPHIC VARIABLES OF THE CLIENTS IN EXPERIMENTAL AND CONTROL GROUP.

Table 4.1.1 : Frequency and percentage distribution of demographic variables such as age, gender and religion in the experimental and control group.

N=60

S.No.	Demographic Variables	Experimental Group		Control Group	
		No.	%	No.	%
1.	**Age in years**				
	40 – 49	9	30.00	9	30.00
	50 – 59	11	36.67	11	36.67
	≥60	10	33.33	10	33.33
2.	**Gender**				
	Male	11	36.67	11	36.67
	Female	19	63.33	19	63.33
3.	**Religion**				
	Hindu	25	83.33	25	83.33
	Muslim	1	3.33	1	3.33
	Christian	4	13.33	4	13.33
	Others	0	0.00	0	0.00

Table 4.1.1 depicts the frequency and percentage distribution of demographic variables such as age, gender and religion in the experimental and control group.

In the experimental group and control group, with regard to the age in years, 11(36.67%) were in the age group of 50 to 59 years, 19(63.33%) of them were female and 25 (83.33%) belongs to Hindu religion.

Table 4.1.2: Frequency and percentage distribution of demographic variables such as educational status, occupation and family income in the experimental and control group.

N=60

S.No.	Demographic Variables	Experimental Group		Control Group	
		No.	%	No.	%
1.	**Educational Status**				
	Non-literate	13	43.33	13	43.33
	Primary education	10	33.33	10	33.33
	High or higher schooling	6	20.00	6	20.00
	Diploma/Degree	1	3.33	1	3.33
	Post graduate and above	0	0.00	0	0.00
2.	**Occupation**				
	Unemployed/Retd	21	70.00	21	70.00
	Semi skilled	9	30.00	9	30.00
	Skilled	0	0.00	0	0.00
	Professionals	0	0.00	0	0.00
3.	**Family income per month**				
	Rs.2,000-Rs.5,000	15	50.00	15	50.00
	Rs.5,001 - Rs.10,000	15	50.00	15	50.00
	>10,000	0	0.00	0	0.00

Table 4.1.2 depicts the frequency and percentage distribution of demographic variables such as educational status, occupation and family income in the experimental and control group.

In the experimental group and control group, with regard to the educational status 13(43.33%) were non literate, 21(70%) of them were unemployed and 15(50%) had family income of Rs.2, 000-Rs.5,000 and Rs. 5,001-Rs.10,000 per month .

Table 4.1.3: Frequency and percentage distribution of demographic variables such as duration of diabetes mellitus, duration of neuropathy pain, treatment for diabetes mellitus and suffering from any co-morbid illness in the experimental and control group.

N=60

S.No.	Demographic Variables	Experimental Group		Control Group	
		No.	%	No.	%
1.	**Duration of diabetes mellitus**				
	<2 years	3	10.00	3	10.00
	2 - 5 years	13	43.33	13	43.33
	More than 5 years	14	46.67	14	46.67
2.	**Duration of neuropathy pain**				
	<6 months	13	43.33	13	43.33
	6 months - 1 year	12	40.00	12	40.00
	More than 1 year	5	16.67	5	16.67
3.	**Treatment for Diabetes mellitus**				
	Oral hypoglycemic agent	23	76.67	23	76.67
	Insulin	2	6.67	2	6.67
	Both	5	16.67	5	16.67
4.	**Suffering from any co-morbid Illness**				
	Yes	4	13.33	4	13.33
	No	26	86.67	26	86.67

Table 4.1.3 depicts the frequency and percentage distribution of demographic variables such as duration of diabetes mellitus, duration of neuropathy pain, treatment for diabetes mellitus and suffering from any co-morbid illness in the experimental and control group.

In the experimental group and control group, with regard to the duration of diabetes mellitus, 14(46.67%) were belongs to more than 5 years, 13(43.33%) of them had neuropathy pain with the duration of < 6 months, 23(76.67%) were under the treatment of oral hypoglycemic agents and 26 (86.67%) were not suffering from any co morbid illness .

SECTION 4.2: ASSESSMENT OF PRE-TEST AND POST-TEST LEVEL OF NEUROPATHY PAIN AMONG CLIENTS WITH DIABETES MELLITUS IN THE EXPERIMENTAL GROUP AND CONTROL GROUP.

N=60

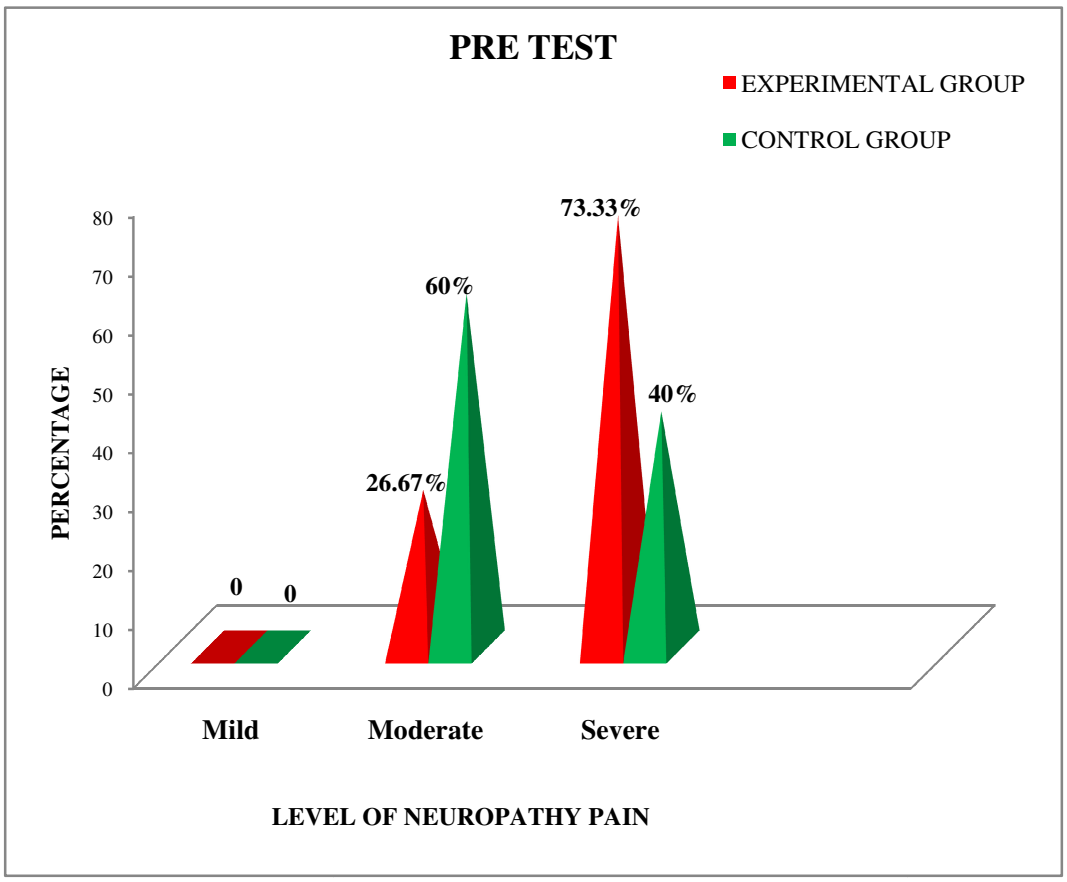


Figure 4.2.1 Frequency and percentage distribution of pretest level of neuropathy pain among clients with diabetes mellitus in the experimental group.

The above figure shows the pretest level of neuropathy pain, in experimental group, 22(73.33%) had severe level of neuropathy pain, 8(26.67%) had moderate level of neuropathy pain and none of them had mild level of neuropathy pain. Whereas in the control group 18 (60%) had moderate level of neuropathy pain, 12(40%) had severe level of neuropathy pain and none of them had mild neuropathy pain.

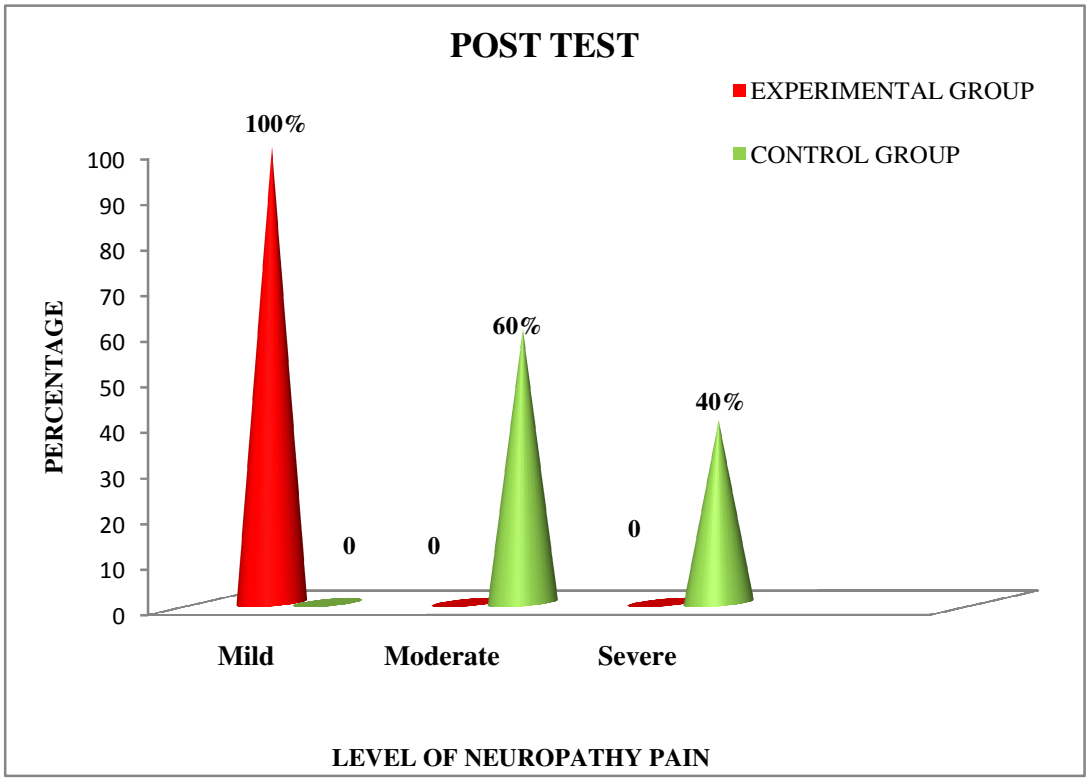


Figure 4.2.2: Frequency and percentage distribution of post test level of neuropathy pain among clients with diabetes mellitus in the experimental group and control group

The above figure shows the post test level of neuropathy pain, in experimental group 30(100%) had mild level of neuropathy pain, and none of them had moderate and severe level of neuropathy pain. Whereas in the control group 18(60%) had moderate level of neuropathy pain, 12(40%) had severe level of neuropathy pain and none of them had mild neuropathy pain.

Figure 4.2.1 and 4.2.2 depicts the pretest and post test level of neuropathy pain among clients with diabetes mellitus in the experimental group and control group which revealed that there is a significant reduction in the level of neuropathy pain in the post test among experimental group.

SECTION 4.3: COMPARISON OF PRETEST AND POSTTEST LEVEL OF NEUROPATHY PAIN AMONG CLIENTS WITH DIABETES MELLITUS IN THE EXPERIMENTAL GROUP AND CONTROL GROUP.

Table.4.3.1 : Comparison of pre-test and post-test level of neuropathy pain in the experimental group

n=30

Neuropathy Pain	Mean	S.D	Paired 't' value
Pre Test	81.20	7.54	t = 41.671***
Post Test	21.93	5.44	p = 0.001(S)

***P<0.001, S-Significant

Table.4.3.1 illustrates the comparison of pre-test and post-test level of neuropathy pain in the experimental group.

The comparison reveals that the pre-test mean score was 81.20 with a standard deviation of 7.54 and the post test mean value was 21.93 with SD of 5.44. The calculated 't' value 41.671 was higher than the table value which indicated that there was a high statistical significant difference in the pre and post test level of neuropathy pain among clients with diabetes mellitus in experimental group at p<0.001 level. This finding of the study revealed that the contrast bath had an effective in reducing the level of neuropathy pain.

Hence the mean differed score 59.27 and 't' value showed high level of significance.

Table 4.3.2: Comparison of pre-test and post-test level of neuropathy pain in the control group

n=30

Neuropathy Pain	Mean	S.D	Paired 't' value
Pre Test	74.67	6.79	t = 2.001
Post Test	72.73	7.15	p = 0.055(N.S)

P<0.05, N.S-Not Significant

Table.4.3.2 depicts the comparison of pre-test and post-test level of neuropathy pain in the control group.

The comparison of the pre test and post test level of neuropathy pain within the control group revealed that, the pre-test mean value was 74.67 with SD of 6.79 and the post test mean value was 72.73 with SD of 7.15. The calculated 't' value 2.001 was higher than the table value which indicated that there was a low statistical significant difference in the pre test and post test level of neuropathy pain among control group at p<0.055 level.

Table 4.3.3 Comparison of pretest level of neuropathy pain score among clients with diabetes mellitus between the experimental and control group

N=60

Pre Test	Mean	S.D	Unpaired 't' value
Experimental Group	81.20	7.54	t = 3.526***
Control Group	74.67	6.79	p = 0.001(S)

***p<0.001, S – Significant

Table.4.3.3 depicts the comparison of pretest level of neuropathy pain score among clients with diabetes mellitus between the experimental and control group

In the pre test, the level of neuropathy pain for the experimental group the mean value was 81.20 with SD of 7.54 and mean value for control group was 74.67 with SD of 6.79. The calculated unpaired 't' value 3.526 at p<0.001 level indicated that there was a high statistical significant difference in the pre test level of neuropathy pain score among clients with diabetes mellitus between the experimental and control group. This finding was suggestive of effectiveness of contrast bath in reducing the level of neuropathy pain.

Table 4.3.4: Comparison of post test level of neuropathy pain score among clients with diabetes mellitus between the experimental and control group

N=60

Post test	Mean	S.D	Unpaired 't' value
Experimental Group	21.93	5.44	t = 30.964***
Control Group	72.73	7.15	p = 0.001(S)

***p<0.001, S – Significant

Table.4.3.4 depicts the comparison of post test level of neuropathy pain score among clients with diabetes mellitus between the experimental and control group.

In the post test, the level of neuropathy pain for the experimental group the mean value was 21.93 with SD of 5.44 and mean value for control group was 72.73 with SD of 7.15. The calculated unpaired 't' value was 30.964 at p<0.001 which indicated that there was a high statistical significant difference in the post test level of neuropathy pain score among clients with diabetes mellitus between the experimental and control group.

The findings of the study proved that the contrast bath is an effective intervention protocol to reduce the level of neuropathy pain among clients with diabetes mellitus.

Table 4.3.1 to 4.3.4 depicts the comparison of pre test and post test level of neuropathy pain among clients with diabetes mellitus in the experimental and control group, which concluded that contrast bath was effective in reducing the level of neuropathy pain among clients with diabetes mellitus.

SECTION 4.4: ASSOCIATION OF SELECTED DEMOGRAPHIC VARIABLES WITH THE MEAN DIFFERED LEVEL OF NEUROPATHY PAIN SCORE AMONG CLIENTS WITH DIABETES MELLITUS IN THE EXPERIMENTAL AND CONTROL GROUP.

Table 4.4.1 : Association of selected demographic variables with the mean differed level of neuropathy pain score among clients with diabetes mellitus in the experimental group

n=30

Demographic Variables	Pre Test		Post Test		Mean Diff.		ANOVA/ Unpaired 't' Value
	Mean	S.D	Mean	S.D	Mean	S.D	
Family income per month							F = 2.751 p = 0.010 S*
Rs.2,000-Rs.5,000	79.13	7.38	23.48	4.01	55.73	7.37	
Rs.5,001 - Rs.10,000	83.27	7.36	20.47	6.38	62.80	6.68	
>10,000	-	-	-	-	-	-	

*p<0.05, S – Significant

Table 4.4.1 shows the association of selected demographic variables with the mean differed level of neuropathy pain score among clients with diabetes mellitus in the experimental group.

The calculated F value 2.751 indicated that there was a significant association at p<0.010 level with the demographic variable of family income per month and no significant association with the other demographic variables. The variable which influences the reduction in level of neuropathy pain among clients with diabetes mellitus was family income per month.

In the experimental group, the family income per month has significance this may be unable to spend money for taking treatment.

In the control group none of the demographic variables showed any statistically significant association.

DISCUSSION

The study was conducted to evaluate the effectiveness of contrast bath on level of neuropathy pain among clients with diabetes mellitus attending diabetic outpatient department.

This chapter discusses in detail the finding of the analysis in relation to the objectives and hypotheses of the study. The following were the objectives of the study and further discussion will exemplify how these objectives were satisfied and how the hypotheses was rejected based on the result of the study.

5.1 Description of the demographic variables of the patients in experimental and control group.

In experimental group and control group, with regard to the age in years, 11(36.67%) were in the age group of 50 to 59 years, 19(63.33%) were female and 25(83.33%) belongs to Hindu religion. With regard to the educational status, 13(43.33%) were non literate, 21(70%) were unemployed and 15 (50%) had family income of Rs.2,000-Rs.5,000 per month .With regard to the duration of diabetes mellitus, 14(46.67%) belongs to more than 5 years, 13(43.33%) had neuropathy pain with the duration of <6 months, 23(76.67%) were under the treatment of oral hypoglycemic agents and 26 (86.67%) were not suffering from any co morbid illness .

5.2 The first objective was to assess and compare the pre and post test level of neuropathy pain among the experimental and control group.

The analysis in figure 4.2.1 showed the pretest level of neuropathy pain, in experimental group, 22(73.33%) had severe level of neuropathy pain, 8(26.67%) had moderate level of neuropathy pain and none of them had mild level of neuropathy pain. Whereas in the control group, 18(60%) had moderate level of neuropathy pain, 12(40%) had severe level of neuropathy pain and none of them had mild neuropathy pain.

The analysis in the figure 4.2.2 shows the post test level of neuropathy pain, in experimental group 30(100%) had mild level of neuropathy pain , and none of them had

moderate and severe level of neuropathy pain. Whereas in the control group, 18(60%) had moderate level of neuropathy pain, 12(40%) had severe level of neuropathy pain and none of them had mild neuropathy pain.

The analysis in table.4.3.1 findings inferred that when comparing the pre test and post test level of neuropathy pain within the experimental group the pre-test mean value was 81.20 with SD of 7.54 and the post test mean value was 21.93 with SD of 5.44. The calculated 't' value 41.671 was higher than the table value which indicated that there was a high statistical significant difference in the pre and post test level of neuropathy pain among experimental group at $p<0.001$ level. This finding was suggestive of effectiveness of contrast bath in reducing the level of neuropathy pain.

The analysis in table 4.3.2 findings inferred that comparing the pre test and post test level of neuropathy pain within the control group, the pre-test mean value was 74.67 with SD of 6.79 and the post test mean value was 72.73 with SD of 7.15. The calculated 't' value 2.001 was higher than the table value which indicated that there was a low statistical significant difference in the pre test and post test level of neuropathy pain among control group at $p<0.05$.

The above findings were consistent with the experimental study conducted by **Jessica Marsh, (2014)** to know the effectiveness of contrast bath among clients with sprains and strains in the ankle and foot at a massage centre, Halifax, Cannada. Investigator did contrast bath alternatively using hot water with 36-38 degrees C(3minutes) and cold water with 4-21 degrees C(10 seconds to 1 minute) for 3 cycles, always ending with cold. The study result reported that there was a reduction in the level of pain in the ankle and foot.

The above study findings were consistent with the quasi experimental study conducted by **Gormans JM et al (2011)** to assess the effectiveness of hydrotherapy among 20 diabetes mellitus clients with foot pain who were admitted in a medical ward were randomly selected. Foot immersion was done in hot water for 3 minutes and cold water for 30 seconds, alternating for 3 cycles. The study finding revealed that there was reduction in foot pain which was noticed by using numerical pain scale.

Hence the null hypothesis **NH_1** stated earlier that **"there is no significant difference between the pre-test and post-test level of neuropathy pain among the experimental and control group"** at $p<0.05$ level was **rejected.**

5.3 The second objective was to compare the pre-test and post test level of neuropathy pain between the experimental and control group

The analysis in table 4.3.3 findings inferred that in the pre test, the level of neuropathy pain for the experimental group the mean value was 81.20 with SD of 7.54 and mean value for control group was 74.67 with SD of 6.79. The calculated unpaired 't' value 3.526 at $p<0.001$ which indicated that there was a high statistical significant difference in the pre test level of neuropathy pain score among clients with diabetes mellitus between the experimental and control group. This finding was suggestive of effectiveness of contrast bath in reducing the level of neuropathy pain.

The analysis in table 4.3.4 findings inferred that in post test , the level of neuropathy pain for the experimental group the mean value was 21.93 with SD of 5.44 and mean value for control group was 72.73 with SD of 7.15. The calculated unpaired 't' value was 30.964 at $p<0.001$ which indicated that there was a high statistical significant difference in the post test level of neuropathy pain score among clients with diabetes mellitus between the experimental and control group.

The findings of the study was supported by, **Donna E. Breger Stanton et al** (2012) conduced a systematic review among 28 clinical research articles on contrast bath from 1938 onwards in which 10 met the inclusive criteria set by the authors to know the effectiveness of contrast bath on diagnosis of rheumatoid arthritis and diabetes ,to note the physiological temperature variations on blood flow, temperature of subcutaneous, intramuscule, the influence of room temperature, pain and age. The definitive conclusions was made that the contrast bath increases superficial blood flow and skin temperature in foot which relieves pain.

The above study findings were consistent with an experimental study conducted by **Nick Grantham (2008)** to know the effectiveness of contrast bath among 60 clients with diabetes foot attending foot clinic at china. They took 30 minutes for each client to

provide the intervention. The temperature of the hot water was 35-40 degree C for 3-4 minutes and cold water was 10-15 degree C for 3-4 times. They concluded the study as contrast bath stimulates the nervous system since brain receives and recognises various information(hot and cold), hence it reduces pain due to temperature variations.

The conceptual framework based on **Wiedenbach's Helping Art of Clinical Nursing Theory** guided the researcher to accomplish the study. This helping art theory aided in ministering the needed help with contrast bath. The investigator perceived the need of implementing the contrast bath on reducing the level of neuropathy pain among clients with diabetes mellitus by administering contrast bath, which includes immersion of feet in warm and cold bath for a duration of 20 minutes(5 cycles).

The clients with diabetes mellitus attending diabetic outpatient department were the recipient in the study, the investigator identified the need by assessing the pretest level of neuropathy pain using Galer Neuropathy Pain Scale and prescribed contrast bath to minister the need of the clients with diabetes mellitus. The goal was to reduce the level of neuropathy pain through the means of contrast bath for 20 minutes(5 cycles). The investigator validated the need by assessing the post test level of neuropathy pain using Galer Neuropathy Pain Scale which revealed that there was reduction in the level of neuropathy pain among clients with diabetes mellitus. The researcher enhanced the contrast bath for those who revealed significant improvement and gave reinforcement for those with insignificant improvement of level of neuropathy pain.

Hence the null hypothesis $\mathbf{NH_2}$ stated earlier that **"there is no significant difference in the pre-test and post-test level of neuropathy pain between the experimental and control group"** at $p<0.05$ level was **rejected.**

5.4 The third objective was to associate the selected demographic variables with the mean differed level of neuropathy pain among clients with diabetes mellitus in the experimental and control group.

The analysis in table 4.4.1 findings inferred that in the experimental group the analysis using ANOVA revealed a low statistical significance with regard to family income at $p<0.010$ level, and no statistical significance for any of the other selected demographic variables such as age, gender, occupation, religion, educational status,

duration of diabetes mellitus and neuropathy pain, treatment for diabetes mellitus, suffering from any co morbid illness. In control group the analysis using ANOVA revealed no statistical significance for all the selected demographic variables.

Hence the null hypothesis **NH_3** stated earlier that "**there is no significant association of selected demographic variables with the mean differed level of neuropathy pain among clients with diabetes mellitus in experimental and control group"** at $p<0.010$ level was **rejected** for family income per month and **accepted** for all other selected demographic variables such as age, gender, occupation, religion, educational status, duration of diabetes mellitus and neuropathy pain, treatment for diabetes mellitus and suffering from any co morbid illness in the experimental group. The null hypothesis **NH_3** was accepted for all the selected demographic variables in the control group.

The above discussions clearly represent that there has been a statistically significant impact of contrast bath on level of neuropathy pain among clients with diabetes mellitus. This draws conclusion for the study that contrast bath can be used as an effective intervention by the neuro nurses, community health nurse, nurse educator, nurse administrator, nurse researcher and health care professionals in reducing the level of neuropathy pain among clients with diabetes mellitus.

SUMMARY, CONCLUSION, IMPLICATIONS, RECOMMENDATIONS AND LIMITATIONS

This chapter presents the summary, conclusion, implications, recommendations and limitations of the study.

6.1 SUMMARY

Contrast bath, also known as alternate bath, allegedly promotes the cyclic vaso constriction and vasodilatation and enhances the reduction of neuropathy pain in clients with diabetes mellitus. Protocols may involve alternate immersion of lower extremities in warm water and cold water. Protocols may differ with respect to who performs the contrast bath and climatic changes in which it is performed. Professionals who may provide the service include nurses, occupational therapists and physical therapists. In some cases, family members and clients may be trained in the techniques and are given primary responsibility for providing the therapy. Treatment may be delivered in the hospital, the patient's home or in a nursing home.

The present study was conducted to assess the effectiveness of contrast bath on level of neuropathy pain among clients with diabetes mellitus in outpatient department at selected hospitals, Chennai. The findings of the study evidenced that there was an effectiveness of contrast bath among clients with diabetes mellitus attending diabetic outpatient department.

6.1.1 The objectives of the study were

1. To assess and compare the pre and post test level of neuropathy pain among the experimental and control group.
2. To compare the pre-test and post test level of neuropathy pain between the experimental and control group.
3. To associate the selected demographic variables with mean differed level of neuropathy pain in experimental and control group.

6.1.2 The assumptions made were

1. Clients with diabetes mellitus may have neuropathy pain.
2. Contrast bath may reduce the neuropathy pain in clients with diabetes mellitus

6.1.3 The null hypotheses formulated were

NH_1- There is no significant difference between the pre-test and post-test level of neuropathy pain among the experimental and control group.

NH_2- There is no significant difference in the pre-test and post test level of neuropathy pain between the experimental and control group.

NH_3- There is no significant association of the selected demographic variables of mean differed level of neuropathy pain in experimental and control group.

The review of literature was retrieved from primary and secondary sources, Investigator's professional experience and expert guidance from the field of medical-surgical nursing helped the investigator as the basis for the selection of the problem, design the methodology and formulation of tool for data collection and conceptual framework.

The conceptual framework for the study was based on the modified **WIEDENBACH'S HELPING ART CLINICAL NURSING THEORY** and it provided a comprehensive framework for achieving the objectives of the study. The framework portrays that a positive outcome promotes the nurses action in reducing the level of neuropathy pain among clients with diabetes mellitus and also helps to evaluate the process of the study at each step.

The researcher adopted a Experimental between group pretest post test design to assess the effectiveness of contrast bath on neuropathy pain among clients with neuropathy pain. The study was conducted among the clients attending diabetic outpatient department at Sir Ivan Stedeford hospital, Chennai.

The content validity of the data collection tool and intervention tool was obtained from 2 medical experts and 4 nursing experts in the field of medical surgical.

The reliability of the tool was established by test retest method (Galer neuropathy pain scale) to assess the level of neuropathy pain . The reliability score was r=0.8 .The 'r' value indicated the highly positive correlation, which showed that the tool is reliable, feasible and practicable to conduct the main study.

The data collection for the main study was done at Diabetic Outpatient Department at Sir Ivan Stedeford Hospital, Chennai. Clients who fulfilled the sample selection criteria were selected by using simple random sampling technique and sample size was 60 (30 each in experimental and control group). The ethical aspects were maintained throughout the study.

Data collected was analyzed and interpreted based on the objectives and null hypotheses using descriptive and inferential statistics. The findings revealed that there was a significant difference in the level of neuropathy pain between experimental and control group.

6.1.4 The major findings of the study revealed that

In the post test, the experimental group, mean level of neuropathy pain score was 2.93 with S.D 5.44 and in the control group, the mean level of neuropathy pain score was 72.73 with S.D 7.15. The calculated unpaired 't' value of 30.964 revealed high statistical significance at $p<0.001$ level.

6.2 CONCLUSION

The present study was conducted to assess the effectiveness of contrast bath on level of neuropathy pain among clients with diabetes mellitus in diabetic outpatient department at Sir Ivan Stedeford Hospital, Chennai. The result of the study projected that there was a statistically significant difference in the pretest and posttest level of neuropathy pain when compared between the experimental and control group, with the experimental group revealing that the contrast bath administered to them was indeed effective in reducing their level of neuropathy pain. Thus they expressed a greater level of comfort and also assured that they will practice it regularly in their homes.

6.3 IMPLICATIONS

The investigator had drawn the following implications from the study, which is of vital concern in the field of Nursing practice, Nursing Administration, Nursing Education and Nursing Research.

6.3.1 Nursing Practice

- The contrast bath has to be incorporated into the routine nursing care to reduce the level of neuropathy pain, to improve the neurological status and thereby to reduce further complications.
- To practice contrast bath, nurses should acquire adequate knowledge, skill and critical thinking.
- Neuronurse specialist can formulate separate protocol for contrast bath and implement in their daily routine.

6.3.2 Nursing Education

- Strengthening the nursing curriculum to exceed the nurses knowledge regarding contrast bath to reduce the level of neuropathy pain.
- The intervention is cost effective, reliable and can be easily incorporated in all nursing specialties.

6.3.3 Nursing Administration

- The neuro nurse administrator has the vital role to insist the nurses to incorporate the contrast bath as a routine care in diabetic outpatient department and ward and there by allocating the needed resources for it.
- The nurse administrator can allot separate budget for inservice education to disseminate the research findings to all nurses

6.3.4 Nursing Research

- The findings of the study can be disseminated to the clinical personnel's and student nurses through website, journals etc.
- Further research has to be encouraged in various settings.
- Nursing research is a powerful means of solving issues and helps the professional nurses and student nurses in finding better ways of promotion of

health and quality of life, prevention of illness and rendering rehabilitation services to all people.

6.4 RECOMMENDATIONS

The study recommends the following for further research.

1. The study will be communicated to the administrative authority of Sir Ivan Stedeford Hospital, Chennai to communicate the practice of contrast bath to the diabetic patients after recommendation from ICCR.
2. The contrast bath can be applicable for diabetic neuropathy clients and all other clients with peripheral neuropathy pain.
3. Comparative study can be conducted to assess the effectiveness of contrast bath.
4. Single case study method can be used.
5. A similar study can be replicated on a larger sample.
6. A quasi experimental study related to knowledge and practice of contrast bath can be conducted in the outpatient department and in wards.
7. The contrast bath can be practiced in all community settings.
8. The investigator recommends the use of contrast bath to the affiliated hospitals of Omayal Achi College Of Nursing.
9. The contrast bath can be adviced to practice for twice or thrice a day, with the temperature of 100-110°F for warm water(3-5 minutes) and cold water temperature of 60-70°F (1-3 minutes) by alternate immersion of feet and should be repeated for 5 times with the total duration of 20-25 minutes.

6.5 LIMITATION

Investigator found difficulty regarding explanation of pain scale during the study.

6.6 PLAN FOR RESEARCH DISSEMINATION

The research findings will be disseminated through paper and poster presentations both in National and International level conferences and published in Journals like Journal of Neurologic Nursing, Journal of Trends in Neuro Sciences and Journal of Neuro Rehabilitation.

6.7 PLAN FOR RESEARCH UTILIZATION

The research findings will be utilized by various hospitals as their routine nursing care in neuro and diabetic settings.

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APPENDIX-C

REQUISITION LETTER FOR CONTENT VALIDITY

From

Karthiga.K,

M.sc Nursing I year,

Omayal Achi College of Nursing,

Chennai.

To

Respected madam,

Subject: Requisition from expert opinion for content validity.

I am Karthiga.k doing my M.sc Nursing I year specializing in Medical Surgical Nursing at Omayal Achi College of Nursing. As a part of my research project to be submitted to the Tamilnadu Dr.M.G.R. Medical University and in partial fulfillment of the university requirement for the award of M.sc Nursing degree, I am conducting **"A study to assess the effectiveness of contrast bath on level of neuropathy pain among clients with diabetes mellitus attending diabetic outpatient department at selected hospitals, Chennai.** I have enclosed my data collection and intervention tool for your expert guidance and validation. Kindly do the needful.

Thanking you

Yours faithfully,

Karthiga.K

ENCLOSURES:

-Research proposal

-Data collection tool

-Intervention tool

-Content validity form

-Certificate for co

LIST OF EXPERTS FOR CONTENT VALIDITY

MEDICAL EXPERTS:

1. **Dr. (col),RAJMAHENDRAN,**
   B.Sc, M.B.B.S, DMCH, PGDHSC, (Diabetology), FCD
   Chief Manager, Hospital Administrator,
   Sir Ivan Stedeford Hospital,
   Ambattur. Chennai- Tamil Nadu.

2. **Dr.DEEPAK ARJUN DAS**
   MD.(Med),DM(Neuro),
   Dip.Neuro(London),FRSH(London),
   Vijaya Health Centre,Vadapalani,
   Chennai,-600026,Tamil Nadu.

MEDICAL SURGICAL NURSING EXPERTS

1. **Mrs. Hema Suresh, M.Sc (N),**
   Vice Principal,
   Meenakshi College of Nursing, Chikkarayapuram,
   Chennai.

2. **Mrs. Jaslina Gnanarani,**
   Reader,
   Apollo College of Nursing,
   Chennai.

3. **Mrs.D.Sasikala,**
   Reader,
   Apollo College of Nursing,
   Chennai.

4. **Mrs.Bindhu Sebastian,**
   Assistant professor,
   St.Thomas College of Nursing,
   Changanacherry, Kerala.

APPENDIX – E

INFORMED CONSENT REQUISITION FORM

Good morning,

I am Ms. Karthiga.K, I-year, M.Sc.,(N) student from Omayal achi college of nursing, Puzhal, Chennai. As a partial fulfilment of the course, I am conducting "A study to assess the effectiveness of contrast bath on level of neuropathy pain among clients with diabetes mellitus attending diabetic outpatient department at selected hospitals, Chennai". Kindly co-operate with me, by giving frank answers to my questions, your answers will be kept confidential and will be used only for my study.

Thank you.

Signature of the investigator

Karthiga.K

INFORMED CONSENT FORM

I understand that I am being asked to participate in a research study conducted by Ms.Karthiga.K, M.sc Nursing 1st year Omayal Achi College of Nursing, Puzhal. This research study will evaluate **"Effectiveness of contrast bath on level of neuropathy pain among clients with diabetes mellitus attending diabetic outpatient department at selected hospitals, Chennai.** If I agree to participate in the study, I will be given structured questionnaire to know the demographic variable and I will be assessed with Galer neuropathic pain scale. The answers will be kept confidential. No identifying information will be included during the analysis process. I understand that there are no risks associated with this study.

I realize that I may participate in the study if I am having diabetes mellitus with neuropathic pain. I realize that I will be benefited by this study. I realize that my participation in this study is entirely voluntary and I may withdraw from the study at any time I wish. If I decide to discontinue my participation in this study, will be continued to be treated in the usual and customary fashion.

I understand that all study information will be kept confidential. However , this information may be used in nursing publication or presentations. If I need to, I can contact Ms. Karthiga.K, M.sc Nursing 1st year Omayal Achi College of Nursing Puzhal, phone no:04426501617 at any time during the study.The study has been explained to me. I have read and understood the consent form, my entire question has been answered, and I agree to participate. I understand that I will be given a copy of this signed consent form.

---------- ----------

Signature of participant Signature of participant

date:---------- date:----------

ஒப்புதல் படிவம்

வணக்கம்,

கார்த்திகா.கு ஆகிய நான் புழலில் உள்ள உமையாள் ஆச்சி செவிலியர் கல்லூரியில் முதுகலை பட்டப்படிப்பு பயின்று வருகின்றேன். என் படிப்பின் ஒரு பகுதியாக நீரிழிவு நோயாளிகளுக்கு அளிக்கப்படும் கான்ட்ராஸ்ட் பாத்தினால் நரம்பு சம்பந்தமான வலியை அளக்கும் அளவையை வடிவமைத்துள்ளேன்.

தயவு செய்து நீங்கள் என்னுடன் ஒத்துழைக்குமாறு வேண்டிக் கொள்கிறேன். நான் உங்களிடம் இருந்து பெற்ற தகவல்களை எக்காரணத்தைக் கொண்டும் வெளியிட மாட்டேன் என்று உறுதி அளிக்கிறேன்.

நன்றி!

உமையாள் ஆச்சி செவிலியர் கல்லூரி, சென்னை-66.

முன் அறிவிப்பு ஒப்பந்த படிவம்

உமையாள் ஆச்சி செவிலியர் கல்லூரியின் சார்பில் செல்வி.கார்த்திகா.கு முதுநிலை இரண்டாம் ஆண்டு மாணவி நடத்தும் இந்த ஆய்வில் என்னை பங்கேற்க கேட்டுக் கொண்டதை நான் ஏற்றுக்கொள்கிறேன்.

இந்த ஆராய்ச்சியின் மூலம் நீரிழிவு நோயாளிகளுக்கு நரம்பு சம்பந்தமான வலியை குறைக்க கான்ட்ராஸ்ட் பாத் அளிக்கப்படும்.

இந்த ஆய்வுக்கு நான் ஒப்புக் கொண்டால் அதனைத் தொடர்ந்து என்னிடம் கேள்விகள் கேட்கப்படும் என்பதை நான் அறிவேன். என்னிடம் கேட்கப்படும் கேள்விகள் அனைத்தும் பதிவு செய்யப்பட்டு பாதுகாக்கப்படும் என்பதை நான் அறிவேன். என்னைப் பற்றிய சேகரித்த சுய தகவல்கள் அனைத்தும் வெளியிடப்படாமல் ஆய்வு மேற்கொள்ளப்படும் என்பதை நான் அறிவேன்.

இந்த ஆய்வின் மூலமாக எனக்கு எந்த பாதிப்பும் இல்லை என்பதை அறிந்து கொண்டேன்.

எதிர்காலத்தில் இந்த ஆய்வின் முடிவுகள் எனக்கோ அல்லது பிற மக்களுக்கோ பயன்படும் என்பதை நான் அறிவேன்.

நான் எவரின்/யாருடைய கட்டாயத்தின் பெயரிலோ அல்லது வற்புறுத்தலின் பெயரிலோ ஆய்வில் பங்கு கொள்ளவில்லை என்பதையும், தேவைப்பட்டால் நான் ஆய்விலிருந்து விலகிக்கொள்ளவும் எனக்கு முழு உரிமை உண்டு என்பதையும் அறிவேன். அவ்வாறு ஆய்விலிருந்து விலகிக் கொள்ளும்பட்டத்திலும் எப்போதும் பிறரைப் போலவே நடத்தப்படுவேன் என்பதை அறிவேன்.

என்னைப் பற்றிய அனைத்து தகவல்களும் இரகசியமாக பாதுகாக்கப்படும் என்பதை அறிவேன். தேவைப்படும்போது ஆய்வின் முடிவுகள் செவிலியர் சார்ந்த பத்திரிகைகளிலும், கருத்தரங்குகளிலும் வெளியிட முழு சம்மதம் அளிக்கிறேன். தேவைப்படும்போது எப்போது வேண்டுமானாலும் ஆய்வில் பங்குக்கொள்ள சம்மதம் அளிக்கிறேன்.

இந்த ஆய்வினைப் பற்றிய சந்தேகங்களைத் தெளிவுபடுத்திக் கொள்ள உமையாள் ஆச்சி செவிலியர் கல்லூரி, புழலில் முதுநிலை இரண்டாம் ஆண்டு பயிலும் மாணவி செல்வி.கார்த்திகா.கு வை எப்போது வேண்டுமானாலும் தொடர்பு கொள்ளலாம் என்பதை அறிவேன்.

இந்த ஆய்வினை பற்றிய முழு விளக்கமும் எனக்கு அளிக்கப்பட்டிருக்கிறது. அதனை நான் முற்றிலுமாக புரிந்துக்கொண்டு ஆய்வில் பங்குக்கொள்ள சம்மதம் அளிக்கிறேன்.

பங்குகொள்பவரின் கையொப்பம் **தேதி:**

ஆராய்ச்சியாளரின் கையொப்பம் **தேதி:**

APPENDIX – F

RESEARCH TOOL

PART-1 DEMOGRAPHIC VARIABLES:

1) Age in years
   a) 40-49
   b) 50-59
   c) ≥60

2) Gender
   a) Male
   b) Female

3) Religion
   a) Hindu
   b) Muslim
   c) Christian
   d) Others

4) Educational status
   a) Non-literate
   b) Primary education
   c) High or higher schooling
   d) Diploma/degree
   e) Post graduate and above

5) Occupation
   a) Unemployed / Retd
   b) Semi skilled
   c) Skilled
   d) Professionals

6) Family income per month

a) Rs.2, 000-Rs.5, 000

b) Rs.5, 001-Rs.10, 000

c) >10,000

7) Duration of diabetes mellitus

a) < 2 years

b) 2-5years

c) More than 5 years

8) Duration of neuropathy pain

a) ≥ 6 months

b) 6months to 1 year

c) more than 1 year

9) Treatment for diabetes mellitus

a) Oral hypoglycemic agent

b) Insulin

c) Both

10) Suffering from any co morbid illness

Yes/ no, if yes mention it

PART – II

GALER NEUROPATHY PAIN SCALE

ITEM	COMPONENTS	SCORE
1.Intensity of pain	No pain to The most intense pain sensation imaginable	0 to 10
2. Sharpness of pain	Not sharp to The most sharp sensation imaginable(like a knife)	0 to 10
3.Level of heat	Not hot to The most hot sensation imaginable(on fire)	0 to 10
4.Dullness	Not dull to The most dull sensation mmaginable	0 to 10
5.Coldness	Not cold to The most cold sensation imaginable(freezing)	0 to 10
6.Skin integrity	Not sensitive to The most sensitive sensation imaginable(raw skin)	0 to 10
7.Level of itching	Not itchy to The most itch sensation imaginable like a mosquito bite	0 to 10

ITEM	COMPONENTS	SCORE
8.Quality of pain	Background pain to Single type pain all the time or only sometimes	0 to 10
9.Overall unpleasantness	Not unpleasant to The most unpleasant sensation imaginable(intolerable)	0 to 10
10. Intensity of deep and surface	No intensity of deep and surface to The most intense deep and surface pain sensation imaginable	0 to 10

SCORING:

Total score is 100. The score is graded as follows:

- ≤ 50 - Mild neuropathy pain
- 51-75 - Moderate neuropathy pain
- >75 - Severe neuropathy pain

APPENDIX – G

PLIAGIARISM REPORT

Plagiarism Detector - Originality Report

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Signature of the Student **Signature of the Principal**

APPENDIX – H

CODING FOR THE DEMOGRAPHIC VARIABLES

Demographic Variables	Code No/
1) Age in years	
a) 40-49	1
b) 50-59	2
c) ≥60	3
2) Gender	
a) Male	1
b) Female	2
3) Religion	
a) Hindu	1
b) Muslim	2
c) Christian	3
d) Others	4
4) Educational status	
a) Non-literate	1
b) Primary education	2
c) High or higher schooling	3
d) Diploma/degree	4
e) Post graduate and above	5
5) Occupation	
a) Unemployed / Retd	1
b) Semi skilled	2
c) Skilled	3
d) Professionals	4

6) Family income per month

a) Rs.2, 000-Rs.5, 000 1

b) Rs.5, 001-Rs.10, 000 2

c) >10,000 3

7) Duration of diabetes mellitus

a) < 2 years 1

b) 2-5years 2

c) More than 5 years 3

8) Duration of neuropathy pain

a) ≥ 6 months 1

b) 6months to 1 year 2

c) more than 1 year 3

9) Treatment for diabetes mellitus

a) Oral hypoglycemic agent 1

b) Insulin 2

c) Both 3

10) Suffering from any co morbid illness

Yes/ no, if yes mention it 1

NEUROPATHY PAIN SCALE

1. INTENSITY OF PAIN

No pain sensation | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most intense pain imaginable

2. SHARPNESS OF PAIN

Not sharp | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most sharp sensation Imaginable ("like a knife")

3. LEVEL OF HEAT

Not hot | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most hot sensation imaginable ("on fire")

4. DULLNESS

Not dull | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most dull sensation imaginable

5. COLDNESS

Not cold | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most cold sensation imaginable ("freezing")

6. SKIN INTEGRITY

Not sensitive | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most sensitive sensation imaginable ("raw skin")

7. LEVEL OF ITCHING

Not itchy | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most itchy sensation imaginable (like a mosquito bite)

8. QUALITY OF PAIN

Background pain | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Single type pain all the time or only sometimes

9. OVERALL UNPLEASANTNESS

Not unpleasant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most unpleasant sensation imaginable (intolerable)

10. INTENSITY OF DEEP AND SURFACE PAIN

No intensity of deep and surface pain

0	1	2	3	4	5	6	7	8	9	10

The most intense deep and surface pain sensation imaginable

APPENDIX – J

INTERVENTION PROTOCOL

PRELIMINARY PREPARATION

Preliminary preparation is needed to provide the intervention in an effective and systematic manner. It comprises of the following.

I.CLIENT PREPARATION

Sl.No.	Nursing action	Rationale
1.	Explain the procedure to the client and obtain informed consent.	To ensure cooperation.
2.	Assess the pre test level of neuropathy pain using Galer neuropathy pain scale.	To recognize the level of neuropathy pain.

II. PREPARATION OF ARTICLES

-Arrange all the needed articles near the client.

-Articles needed are,

Sl.No.	Articles needed	Rationale
1.	Basins -2	To place the clients feet.
2.	Bath thermometer- 1	To check the temperature of hot and cold water.
3.	Kettle -2	To take hot and cold water.
4.	Recording articles	To record the patient level of neuropathy pain.

PREPARATION OF THE HOT AND COLD WATER

Hot water was prepared with the help of sterilizer and cold water with the ice cubes along with refrigerated water. The hot water and cold water were discarded after single use.

PROCEDURE

CONTRAST BATH

Make the client to sit comfortable in the treatment room, place the clients feet in hot water basin for 3 minutes followed by cold water basin for 1 minute. This will produce cyclic vasoconstriction and vasodilatation leads to decreased perception of pain.

DURATION

20 minutes (5 cycles)

DURING THE INTERVENTION

- Assess the clients tolerance to hot and cold.
- Assess the temperature of hot and cold water.

AFTER THE PROCEDURE

Post test level of neuropathy pain is assessed using Galer neuropathy pain scale.

AFTER CARE

- Dry the feet of the client and make them comfort.
- Wash and replace the articles for next use.
- Recording.

CONCLUSION

Contrast bath can be used as an effective nursing intervention in the reduction of neuropathy pain among clients with diabetes mellitus.

APPENDIX – K

DISSERTATION EXECUTION PLAN – GANTT CHART

S.NO	ACADEMIC CALENDER MONTHS	OCTOBER 2012 to SEPTEMBER 2013												OCTOBER 2013 to SEPTEMBER 2014											
		O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S
A	**Conceptual phase**																								
1	Problem identification																								
2	Literature review																								
3	Clinical fieldwork																								
4	Theoretical framework																								
5	Hypothesis formulation																								
B	**Design & planning phase**																								
6	Research design																								
7	Intervention protocol																								
8	Population specification																								
9	Sampling plan																								
10	Data collection plan																								
11	Ethics procedure																								
12	Finalization of plans																								
C	**Empirical phase**																								
13	Data collection																								
14	Data preparation																								
D	**Analytical phase**																								
15	Data analysis																								
16	Interpretation of results																								
E	**Dissemination phase**																								
17	Presentation or report																								
18	Utilization of findings																								
	Calendar months	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9